University of Alberta

Independence, Impartiality and Accreditation of Research Ethics Boards

by

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Abstract

Research Ethics Boards (REBs), also known as Institutional Review Boards (IRBs) in the United States, conduct ethical peer reviews of proposed research involving human subjects. This thesis provides a history and description of REBs, and describes their governance. It examines the legal principles of independence and impartiality, and applies those principles to REBs at the University of Alberta. It argues that independence and impartiality would be enhanced if a Canadian national system of accreditation of institutions hosting REBs were instituted, the organizational placement of REBs within the University were altered, and a public reporting system were adopted.

The proposed model is based on the independent judicial commission model developed in Canadian judicial independence jurisprudence, which requires that an arms-length body be interposed between the judiciary (REBs) and the executive (research administration); this body must be independent, effective, and objective.

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Acronyms

AAC	Academic Appeals Committee (University of Alberta)
AAMC	Association of American Medical Colleges
AAS:UA	Association of the Academic Staff: University of Alberta
AHFMR	Alberta Heritage Foundation for Medical Research
APA	American Psychological Association
APC	Academic Planning Committee (University of Alberta)
ASC	Academic Standards Committee (University of Alberta)
ASL REB	Arts Science and Law Research Ethics Board (University of Alberta)
CAUT	Canadian Association of University Teachers
CCHSA	Canadian Council on Health Services Accreditation
CCI	Cross Cancer Institute (University of Alberta)
CEO	Chief Executive Officer
CIHR	Canadian Institutes of Health Research
CIOMS	Council for International Organizations of Medical Sciences
CIUS	Canadian Institute of Ukrainian Studies (University of Alberta)
CLE	Committee on the Learning Environment (University of Alberta)
CLRC	Campus Law Review Committee (University of Alberta)
CMA	Canadian Medical Association
CMAJ	Canadian Medical Association Journal
COSA	Council on Student Affairs (University of Alberta)
CPSA	College of Physicians & Surgeons of Alberta

CPSA RERC	College of Physicians & Surgeons of Alberta Research Ethics Review Committee
CREBA	Community Research Ethics Board of Alberta
CRTC	Canadian Radio & Television Commission
ERSC	Environmental Research & Studies Centre (University of Alberta)
FDC	Facilities Development Committee (University of Alberta)
GAC	General Appeals Committee (University of Alberta)
GCP	General Clinical Procedure
GFC	General Faculties Council (University of Alberta)
HIA	*Health Information Act*
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome
HREC[1]	Human Research Ethics Committee
HRIHS	Governance of Health Research Involving Human Subjects
HRPO	Human Research Protections Office (University of Alberta)
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IRB[2]	Institutional Review Board
JAMA	Journal of the American Medical Association
LSA	Law Society of Alberta
LSD	Lysergic Acid Diethylamide
MRC	Medical Research Council

[1] The Australian equivalent of Research Ethics Boards.
[2] The American equivalent of Research Ethics Boards.

NASA	Non-Academic Staff Association (University of Alberta)
NCEHR	National Council on Ethics in Human Research
NSERC	Natural Sciences and Engineering Research Council
ORCA	Office of Research Certifications and Approvals (University of Alberta)
PEERH	Program Ensuring Ethical Research with Humans
PRB	Practice Review Board (University of Alberta)
PRE	Interagency Advisory Panel on Research Ethics
PSLA	*Post-Secondary Learning Act*
REB	Research Ethics Board
RFO	Research Facilitation Office (University of Alberta)
RSO	Research Services Office (University of Alberta)
SSHRC	Social Sciences and Humanities Research Council
TCPS	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
TEC	Techology, Entrepreneur & Company Edmonton (University of Alberta)
UAB	University Appeal Board (University of Alberta)
UASC	Undergraduate Awards and Scholarship Committee (University of Alberta)
UCHRE	University Committee on Human Research Ethics (University of Alberta)
UNAC	United Nations Association of Canada

UNAIDS	Joint United Nations Programme on HIV/AIDS
UNESCO	United Nations Educational, Scientific & Cultural Organization
UTAC	University Teaching Awards Committee (University of Alberta)
VP	Vice-President
WHO	World Health Organization
WMA	World Medical Association

I. History and Definition of Research Ethics Boards

A. Introduction

"Research Ethics Board" (REB) is the name commonly used in Canada for a decision-making body which determines whether research involving people, more formally called "human subjects" or "research participants," can proceed as proposed by the researcher. Research Ethics Boards are mandated to assess the methodology of proposals and weigh the ethical considerations of the research. Their responsibility is to ensure that people are protected in terms of their physical and emotional well-being, and that their dignity and privacy are respected. In the United States, Research Ethics Boards are typically called "Institutional Review Boards" (IRBs). Sometimes Research Ethics Boards are called Ethics Committees, as in the *Health Information Act*[1] of Alberta, in England, and in Europe.[2] In Australia they are known as Human Research Ethics Committees (HRECs).

To understand current-day Research Ethics Boards, it is useful to have a sense of their historical context and evolution. In this chapter, I will place Research Ethics Boards in the context of the rule of law – which is the foundation of my thesis – explore their history, describe their nature, and identify their main types.

In Chapter 2, I will define and explore the legal concepts of independence and impartiality. In that context I will introduce the three branches of government – the

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[1] R.S.A. 2000, c. H-5, s. 1(1)(j). The *Health Information Act* is being amended to refer to these boards as Research Ethics Boards (see Bill 31 *Health Information Amendment Act, 2006*, 2d Sess., 26th Parl., Alberta 2006, c. 18, cl. 1(1)(v.1) (assented to 24 May 2006)).

[2] The term "Ethics Committee" is also sometimes used to describe committees in hospitals or other health care settings which consult with patients and caregivers on ethical issues or dilemmas. These committees do not review proposed research, and are not Research Ethics Boards.

executive, the legislature, and the judiciary. In accordance with the rule of law, the judiciary must be independent from the other branches of government, as well as from political and other influences. Under the core characteristic of financial security comes the notion of an independent judicial commission which makes recommendations regarding judicial remuneration.

In Chapter 3, I will apply the principles of independence and impartiality to Research Ethics Boards at the University of Alberta. In Chapter 4, I will liken the model of independent judicial commissions to independent accreditors of Research Ethics Boards. I will argue in favor of accreditation as a means of enhancing the independence of Research Ethics Boards. Accreditation is a process of assessing, on an institution by institution basis, the governance of research involving humans based on a number of objective standards (which are currently being defined in Canada). I will focus on the standards pertaining to the organizational placement of Research Ethics Boards. Using the University of Alberta as an example, I will submit that independence and impartiality would be increased if research governance administration and Research Ethics Boards reported to the President directly rather than to the Office of the Vice-President (Research). The Vice-President (Research)'s office is conflicted by the dual role of attracting research funds on one hand and protecting human subjects on the other.

My perspective in this thesis is broader than a purely legal approach. I am addressing governance of research ethics issues from the perspective of political morality, commenting on how things should be from the point of view of ethics and fairness.

B. The Rule of Law

The rule of law is a cornerstone of the Canadian system of government. It is a fundamental principle upon which Canada is founded.[3] An explanation of what is and is not encompassed by the concept of the "rule of law" lies outside the scope of my investigation. For my purposes, three main aspects of the rule of law are important.

First, at an overview level, the rule of law has been understood to entail the following:

- All officials, along with everyone else, are subject to the law (no one is "above the law").[4]
- Governmental authority, the entitlement of government to limit the interests of citizens, must be founded on laws.[5]

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[3] *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 at Preamble [*Charter*]: "Whereas Canada is founded upon principles that recognize the supremacy of God and the rule of law."

[4] A.V. Dicey, *Introduction to the Study of the Law of the Constitution* (London: MacMillan & Co., 1964) at 193: "[E]very man, whatever be his rank or condition, is subject to the ordinary law of the realm and amenable to the jurisdiction of the ordinary tribunals." Expressed another way: "[T]he law is supreme over officials of the government as well as private individuals, and thereby preclusive of the influence of arbitrary power." (*Re Manitoba Language Rights*, [1985] 1 S.C.R. 721 at para. 59). As Senator Eugene Forsey stated:

> [The rule of law] means that everyone is subject to the law; that no one, no matter how important or powerful, is above the law – not the government; not the Prime Minister, or any other Minister, not the Queen or the Governor General or any Lieutenant-Governor; not the most powerful bureaucrat; not the armed forces; not Parliament itself, or any provincial legislature. None of these has any powers except those given to it by the law … If anyone were above the law, none of our liberties would be safe. (*The Rule of Law* (2005), online: Parliament of Canada <http://www.parl.gc.ca/information/library/idb/forsey/rule_of_law_01-e.asp>.)

[5] "[T]he rule of law requires the creation and maintenance of an actual order of positive laws which preserves and embodies the more general principle of normative order." (*Re Manitoba Language Rights*, *ibid.* at para. 60). As well, Professor DeCoste provides a chart entitled "The Anatomy of Law." Institutional requirements of the rule of law are divided into the separation of powers and the regime of rights (defined as a body of public rules to constrain public and private power). The regime of rights has three headings: substantive law, procedure law, and remedial law (each with sub-headings of public law and private law under them). F.C. DeCoste, *On Coming to Law: An Introduction to Law in Liberal Societies* (Markham, Ont.: Butterworths Canada Ltd., 2001) at 173 [DeCoste, *On Coming to Law*].

- Conflicts between citizens, and between citizens and government, must be resolved through legal processes by applying legal rules.[6]
- Laws, or rules, must be general, transparent, known, and understandable. [7]

Second, the operation of the rule of law requires that three functions be fulfilled:

(a) legislative – creating the rules,

(b) executive – carrying out legislative directions and performing governance activities within the law, and

(c) judicial – interpreting the rules.

This last prerequisite function is tied directly to the independence of the judiciary, which serves the social goal of maintaining the rule of law, "one aspect of which is the constitutional principle that the exercise of all public power must find its ultimate source in a legal rule."[8] This function is of particular concern to my thesis and shall be explored further below. I note that the actual institutional framework within which these functions are accomplished is highly variable – for example, the functions are carried out under the Canadian system of responsible government and the American approach of strict separation of powers.

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[6] See Wayne N. Renke, "Invoking Independence: Judicial Independence as a No-cut Wage Guarantee" (1994) 5 Points of View 1 at 3: "Schematically and simplistically, the 'rule of law' involves the resolution of many significant disputes by the impartial application of authoritative general rules."

[7] DeCoste, "*On Coming to Law*," *supra* note 5 at 172 [emphasis in original]: "Rules by their very nature must be *general, clear, publicly accessible, formulated in advance* and *prospective in application*."

[8] *Reference Re Remuneration of Judges of the Provincial Court of Prince Edward Island; Reference Re Independence and Impartiality of Judges of the Provincial Court of Prince Edward Island; R. v. Campbell; R. v. Ekmecic; R. v. Wickman; Manitoba Provincial Judges Association v. Manitoba*, [1997] 3 S.C.R. 3 [*Provincial Judges Reference*] at para. 10. As Professor Dicey has explained, "no [one] is punishable or can be lawfully made to suffer in body or goods except for a distinct breach of law established in the ordinary legal manner before the ordinary courts of the land. In this sense the rule of law is contrasted with every system of government based on the exercise by persons in authority of wide, arbitrary, or discretionary powers of constraint" (Dicey, *supra* note 4 at 188). "At its most basic level, the rule of law vouchsafes to the citizens and residents of the country a stable, predictable and ordered society in which to conduct their affairs. It provides a shield for individuals from arbitrary state action." (*Reference Re Secession of Quebec*, [1998] 2 S.C.R. 217 at para. 70).

Third, while the rule of law and its prerequisite functions are features of "macro-level" government, *i.e.*, of our federal and provincial constitutional systems, they are also organizing features of more local rules systems, such as corporations, clubs, and societies, as well as universities and colleges. That is, the concept of the rule of law embraces not merely "macro" governmental functioning, but all rule-based, ordered, organizational activity.

Research Ethics Boards play judicial and, to a degree, executive roles in the rule-based research ethics activity of universities. To explore these roles, I shall turn to the history and evolution of Research Ethics Boards.

C. The History and Evolution of Research Ethics Boards

1. *History of Ethics Review*

Research Ethics Boards grew out of medicine and the health-related disciplines. Their historical roots stem from the World War II horrors of Nazi concentration camps where human experimentation was carried out ruthlessly on thousands of Jews, gypsies, homosexuals, persons with disabilities, and other minority groups under the guise of medical and scientific research.

Two main documents emerged as a result of this nightmare. They are the forerunners of the *Tri-Council Policy Statement*,[9] the national policy which governs research in Canada at this time. They are the *Nuremburg Code* (1947)[10] and the *Helsinki*

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[9] Canadian Institutes of Health Research, National Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2002), online: Public Works and Government Services Canada, Interagency Panel on Research Ethics <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm> [*Tri-Council Policy Statement*].

[10] "Nuremberg Code" in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Nuremberg, October 1946-April 1949 (Washington, D.C.: United States Government Printing Office, 1949-1953) [*Nuremberg Code*]; reprinted in Jay Katz *et al.*, *Experimentation with Human Beings: The Authority of the Investigator, Subject, Professions, and State in the Human Experimentation*

Declaration (1964).[11] These forerunner documents are important because they establish the principles upon which the *Tri-Council Policy Statement* is founded. They also begin to establish processes and institutions which have culminated in the current day system of research ethics governance.

They provide the historical foundation for key principles that have emerged as central to research ethics, each of which is, on its own, the subject of a whole body of literature. Respecting human dignity is the central, overarching principle. One facet of respecting human dignity is protecting the autonomy of individuals, that is, ensuring that, as much as possible, people involved in research decide for themselves what will and will not be done to them.[12]

a) *Nuremberg Code*

(i) Description

The foundational code for contemporary Research Ethics Boards is the *Nuremberg Code*, which was delineated at the end of the judgment in the Doctors' Trial, or "Medical Case," *United States v. Karl Brandt et al.*,[13] which took place in Nuremberg,

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Process (New York: Russell Sage Foundation, 1972) at 305 and George J. Annas & Michael A. Grodin, *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (New York: Oxford University Press, 1992) at 2.

[11] World Medical Association (WMA) General Assembly, *Declaration of Helsinki* (2004), online: WMA <http://www.wma.net/e/policy/b3.htm> [*Helsinki Declaration*].

[12] The formal process in which individual human subjects agree to participate in research is called giving consent. In addition to assessing consent forms and processes, Research Ethics Boards also apply the principles of beneficence and nonmaleficence, the idea of doing good to others, acting in their best interests, and not hurting them. The concepts of beneficence and nonmaleficence are described in Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics*, 4th ed. (New York: Oxford University Press, 1994); beneficence is discussed at 259f.; nonmaleficence at 189f. It is interesting to note that the "do no harm" principle appears in the *Hippocratic Oath*, which dates back to Hippocrates, who lived around 420 B.C. See Jean McHale, Marie Fox & John Murphy, *Health Care Law: Text, Cases and Materials* (London: Sweet & Maxwell, 1997) at 131.

[13] "The Medical Case" in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Nuremberg, October 1946-April 1949 (Washington, D.C.: United States Government Printing Office, 1949-1953). Excerpts from this judgment are reproduced in Katz, *supra* note 10 at 292-306. The indictment opened as follows, Katz, *ibid.* at 292:

Germany at the Palace of Justice, starting in 1946.[14] This post-war trial was a prosecution of 23 persons (20 doctors and three other officials), highly qualified through medical training, who were indicted for war crimes and crimes against humanity. The trial was heard by a court of American judges.

The indictment recounted allegations of experimentation conducted in the name of scientific or medical research. Examples included, but were not limited to, experiments with high-altitude and low-pressure chambers, freezing, malaria, sulfanilamide, epidemic jaundice, spotted fever (typhus), poison, and sterilization.[15] The experiments were conducted against the will of participants. They resulted in severe pain and suffering, permanent disability and injury, intense agony, and death to hundreds of thousands of Jews and other "asocial" persons (Poles, gypsies, and other minority groups) between 1941 and 1945.[16]

> The United States of America, by the undersigned Telford Taylor, Chief of Counsel for War Crimes, duly appointed to represent said Government in the prosecution of war criminals, charges that the defendants herein participated in a common design or conspiracy to commit and did commit war crimes and crimes against humanity, as defined in Control Council Law No. 10, duly enacted by the Allied Control Council on 20 December 1945.

In the eight month long trial, "there were a total of 85 witnesses, 1,471 documents, and 11,538 pages of transcript" (Annas & Grodin, *supra* note 10 at 4).

[14] Annas & Grodin, *ibid.* at 4: "The trial was Case No. 1 of Military Tribunal I … The trial was conducted under the U.S. military auspices according to the Moscow Declaration on German Atrocities (November 1, 1943 …)."

[15] The high altitude experiments were for the benefit of the German Air Force, and simulated atmospheric changes at high altitudes in low pressure chambers. Many died as a result of these concentration camp experiments involving torture and serious injury. In the freezing experiments, subjects were placed in tanks of ice water for up to three hours and were kept outdoors naked at below freezing temperatures. Healthy experimental subjects were deliberately infected by mosquitoes or extracts of mosquito glands to get malaria, as well as by epidemic jaundice and spotted fever (typhus). The purpose was to learn about the effectiveness of drugs, vaccines, and other chemical substances. Some subjects were secretly administered poison in their food and others were injected with poisonous arrows. The subjects died or were killed. Detailed autopsies were performed and anatomical research was conducted. See Katz, *supra* note 10 at 293-94. For descriptions of numerous experiments, see also Katz, *ibid.* at 3-60.

[16] *Ibid.* at 305.

The judgment, rendered in 1947, made findings of guilt or innocence of each defendant,[17] and ended with ten principles governing the ethics of human experimentation. These points have become known as the *Nuremberg Code*:

Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject that there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

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[17] According to Katz, *ibid.* at 306: "Sixteen of the twenty-three defendants were found guilty of war crimes and crimes against humanity. Seven, including Karl Brandt, Rudolf Brandt, and Joachim Mrugowsky, were sentenced to death by hanging; the other nine, including Seigfried Handloser and Gerhard Rose, to imprisonment varying from ten years to life."

5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.[18]

I note the following respecting the *Code*: first and foremost, the *Code* reveals the central place of consent by referring to it in the first sentence: "The voluntary consent of the human subject is absolutely essential."[19] The article goes on to explain the importance of having legal capacity to give consent, that it not be obtained by coercion, how it has to be informed by the nature, purpose, and duration of the experiment, and the consequences reasonably expected. The matter of consent remains primary in research governance issues today, as a matter of ethics, tort law, and criminal law.

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[18] Annas & Grodin, *supra* note 10 at 4.
[19] *Nuremberg Code*, *supra* note 10, art. 1.

Article 6 refers to risk, a critical issue in research ethics, both historically and in the present. It provides that "the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment."[20] The historic roots of the current iteration of the *Tri-Council Policy Statement*[21] in which distinctions are made between minimal risk and more than minimal risk date back to this proposition.

Article 8 provides that the experiment should be conducted only by scientifically qualified persons. This theme also continues to the present day, and now Research Ethics Boards are charged under the *Tri-Council Policy Statement* to ensure that the persons doing the research are appropriately qualified.

There is no reference to Research Ethics Boards *per se* in the *Nuremberg Code*. This is not surprising, as it is part of a legal judgment whose purpose was determining guilt or innocence of specific Nazi physicians for their participation in nonconsensual human experimentation. Nevertheless, the absence of a process or institutional mechanism through which the principles in the *Code* can be implemented is a deficiency from a rule of law perspective. The rule of law, an element of which is reflected in the maxim *ubi jus, ibi remedium* (where there is a right, there is a remedy)[22] requires that rights be accompanied by remedies.

b) *Helsinki Declaration*

Like the *Nuremberg Code*, the *Helsinki Declaration*[23] was named after the place where it was developed. The *Helsinki Declaration* is regarded as the "cornerstone of

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[20] *Ibid.*, art. 6.
[21] *Supra* note 9.
[22] Bryan A. Garner, ed., *Black's Law Dictionary*, 8th ed. (St Paul, Minn.: Thomson West, 2004).
[23] *Supra* note 11.

research ethics."[24] This policy was first adopted by the World Medical Association – which presents physicians from around the world – in 1964 at the 18th World Medical Assembly.[25] It was formulated to inform doctors in conducting clinical research.

After its initial iteration in 1964, the *Helsinki Declaration* underwent a series of changes and revisions. In all its versions, it dealt with consent and risk, as well as principles doctors must follow to be ethical in their clinical research. With regard to risk, it says that the experiment should have an objective in proportion to the inherent risk to the subject,[26] wording that is reflected in the *Tri-Council Policy Statement* today as the proportionate approach to ethics review.

The *Helsinki Declaration* is the first international code to refer to Research Ethics Boards. That reference first appeared in the 1975 version of the *Helsinki Declaration*. It appeared in Art. 5 on Clinical Research, entitled "Medical Research Combined with Professional Care," in the context of an exception to informed consent:

> If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to *the independent committee*.[27]

That reference to the "independent committee" is key. This is the forerunner of what we now know as a Research Ethics Board. That provision remained the same until 2000, when it was expanded by elaborating on the reasons for which a subject may be unable to give consent, as when the subject is a minor child or some other legally incompetent individual.

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[24] *Ibid.*
[25] Annas & Grodin, *supra* note 10 at 331.
[26] *Ibid.* at 332.
[27] *Ibid.* at 336 [emphasis added].

In 1996 an additional reference to the committee was added as a basic principle in Art. 2, clarifying that the committee was to be independent of the investigator and sponsor, and the committee must conform with the laws of the country where the research was undertaken:

> The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to *a specially appointed committee independent of the investigator* and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.[28]

The role of the committee was also clarified in 2000 to provide that the committee must be independent of "any other kind of undue influence,"[29] a rather broad declaration. The committee's responsibility was broadened to include monitoring of ongoing trials, and there is mention of researchers having to report institutional affiliations, funding, sponsorship, subject incentive information, and serious adverse events, as well as potential conflicts of interest and related matters.[30]

c) Additional Documents

The theme of preserving the human dignity of individuals is a foundational concept informing the governance of contemporary research ethics. The *Universal Declaration of Human Rights*[31] carried forward this principle. It was proclaimed by the General Assembly of the United Nations in 1948.[32] It affirmed basic principles of

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[28] *Helsinki Declaration*, *supra* note 11, art. 2 [emphasis added].
[29] *Ibid.*, art. 13.
[30] *Ibid.*
[31] *Universal Declaration of Human Rights*, GA Res. 217 (III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948).
[32] Canada is a signatory to the *Universal Declaration of Human Rights*. It has profoundly influenced the Canadian legal landscape, particularly constitutional law in the development of the *Charter of Rights and Freedoms*. As the United Nations Association of Canada (UNAC) has noted:

dignity, recognizing that "the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world."[33] It provided that "all human beings are born free and equal in dignity and rights."[34] Subsequent United Nations instruments followed the *Universal Declaration*,[35] and in a similar vein, affirmed the centrality of human dignity as a guiding ideal.[36]

A number of additional influential documents inform the work of Research Ethics Boards more directly, including (i) the American *Belmont Report* (1979),[37] (ii) the Council for International Organizations of Medical Sciences Guidelines (CIOMS)

> The *Universal Declaration of Human Rights* is extremely important for Canadians because it has provided us with a framework of human rights goals and standards to which Canadian legislation, institutions, and society can aspire. Since signing the *Universal Declaration of Human Rights* in 1948, the Canadian government has been very successful in making universal human rights a part of Canadian law. There are currently four key mechanisms in Canada to protect human rights: the *Canadian Human Rights Act*, Human Rights Commissions, and provincial human rights laws and legislation. (Online: UNAC <http://www.unac.org/rights/actguide/canada.html>.)

[33] *Supra* note 31, Preamble.

[34] *Ibid.*, art. 1.

[35] See, for example, the *Covenant on Civil and Political Rights*, 19 December 1966, 999 U.N.T.S. 171, 6 I.L.M. 368 (entered into force 23 March 1976, accession by Canada 19 May 1976), and the *Covenant on Economic, Social and Cultural Rights*, 19 December 1966, 993 U.N.T.S. 3, 6 I.L.M. 360 (entered into force 3 January 1976, accession by Canada 19 May 1976).

[36] The preservation of dignity and prohibitions against human experimentation without consent continued to be reflected in Canada's moral and legal obligations through other conventions and legislation. For example, the *Geneva Convention Relative to the Treatment of Prisoners of War* (12 August 1949, 75 U.N.T.S. 135, Can. T.S. 1965 No. 20 (entered into force 21 October 1950, ratification by Canada 14 May 1965)) known as the *Third Geneva Convention*, was adopted in 1949 by the Diplomatic Conference for the Establishment of International Conventions for the Protection of Victims of War, and came into force in 1950. This *Convention*, to which Canada is a signatory, addresses diverse aspects of the treatment of prisoners of war. In particular, "no prisoner of war may be subjected to physical mutilation or to medical or scientific experiments of any kind which are not justified by the medical, dental or hospital treatment of the prisoner concerned and carried out in his interest" (art. 13). More recently, the *Crimes Against Humanity and War Crimes Act*, S.C. 2000, c. 24, incorporated the Rome Statute of the International Criminal Court into Canadian federal legislation. In that statute, war crimes is defined as grave breaches to the *Third Geneva Convention*, and includes "torture or inhuman treatment, including biological experiments" (Schedule, art. 8, para. 2).

[37] United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research & United States Department of Health Education and Welfare, Office of the Secretary, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, D.C.: Department of Health, Education and Welfare, Office of the Secretary, 1988) [*Belmont Report*].

(1993),[38] (iii) professional codes of conduct, and (iv) other policies, both non-binding[39] and binding.[40]

The evolution of research governance was motivated by the uncovering of unethical human experimentation. The Tuskegee Syphilis Study, as noted in the *Belmont Report*, was a study of impoverished rural African American men with syphilis who were observed but left untreated for several decades, long after standard medication and treatment had been developed. The subjects were never told that they were in a study.[41]

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[38] Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002), online: CIOMS <http://www.cioms.ch/frame_guidelines_nov_2002.htm> [CIOMS Guidelines].

[39] *Belmont Report*, *supra* note 37. CIOMS Guidelines, *ibid.* at 9:

> Since the publication of the CIOMS 1993 Guidelines, several international organizations have issued ethical guidance on clinical trials. This has included, from the World Health Organization, in 1995, *Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products*; and from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), in 1996, *Guideline on Good Clinical Practice*, designed to ensure that data generated from clinical trials are mutually acceptable to regulatory authorities in the European Union, Japan and the United States of America. The Joint United Nations Programme on HIV/AIDS published in 2000 the UNAIDS Guidance Document *Ethical Considerations in HIV Preventive Vaccine Research*.

Although international guidelines do not have the force of law, they are influential in that some must be followed if multi-site trials are undertaken in various countries including Canada.

[40] The American laws and regulations must be followed in some cases by Canadian Research Ethics Boards. For example, the Alberta Cancer Board Research Ethics Board follows American Food and Drug Administration regulations because of the many United States based clinical trials.

[41] See Susan Reverby, *Tuskegee's Truths: Rethinking the Tuskegee Syphilis Study* (Chapel Hill, N.C.: University of North Carolina Press, 2000) for a full and thoughtful account of the study. She states, at 1, referring to the human subjects:

> The men … thought that they were patients of a joint federal and local medical and nursing program at the Tuskegee Institute and the Macon Council health department for their "bad blood", a local idiom that encompassed syphilis as well as anemias. They did not consider themselves subjects since they did not know the study existed. The [United States Public Health Service] followed the men for forty years (from 1932 to 1972), actively keeping them from many forms of treatment (including penicillin when it became available in the late 1940s), never giving them a clear diagnosis, but providing them with the watchful eye of a nurse as well as exams (including a diagnostic spinal tap), placebos, tonics, aspirins, and free lunches. Burial insurance became an additional inducement for their participation. In exchange, the men or their families agreed to allow for autopsies without knowing that the researchers needed to confirm the ravages of syphilis on the men's organs and tissues. Over the years, thirteen reports of the study were published in respectable medical science journals, from the *Journal of Venereal Disease Information* to the *Archives of Internal Medicine*.... [T]he ostensible purpose was to study 'untreated syphilis in the male Negro.'

Dr. Beecher explored 22 cases of research that are considered unethical in his classic article on consent and risk to patients in human experimentation.[42]

A notorious Canadian example of research gone amiss and abuse of research subjects was "the CIA sponsored research on the effects of LSD and other drugs."[43] Patients with mental illnesses were used as experimental subjects without their consent in "scientifically flawed mind-altering experiments by a then world-renowned psychiatrist, Dr Cameron at McGill University's Allan Memorial Hospital in the 1950s."[44]

There are more recent examples as well, such as the case of Dr. Nancy Olivieri, which illustrate the need to be highly vigilant in terms of protecting both human research subjects and researchers. [45]

(i) Belmont Report

The *Belmont Report* responded to a particularly gruesome series of experiments on humans in the United States. The experiments occurred from 1944 to 1974, when

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See also Kathleen Cranley Glass and Trudo Lemmons, "Research Involving Humans" in Jocelyn Grant Downie, Timothy A. Caulfield & Colleen M. Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Toronto: Butterworths, 2002) at 465.

[42] Henry K. Beecher, "Ethics and Clinical Research" (1966) 274:24 New England Journal of Medicine 1354.

[43] Glass & Lemmons, *supra* note 41 at 465.

[44] *Ibid.* at 446, quoting Government of Canada, *News Release: Background Information – Depatterning at the Allen Memorial Institute* (Ottawa: Department of Justice, 17 November 1992) [footnotes omitted].

[45] Dr. Olivieri is a Canadian medical researcher who was participating in a clinical drug trial. A controversy arose when she gave her patients information about life-threatening side effects of the drug that was the subject of the clinical trial. The sponsoring company disagreed with her disclosure of this information to the patients and the medical community (Jennifer L. Gold, "Watching the Watchdogs: Negligence, Liability, and Research Ethics Boards" (2003) 11 Health L. J. 153; Canadian Association of University Teachers (CAUT), "Issues and Campaigns – Dr. Nancy Olivieri," online: CAUT <http://www.caut.ca/en/issues/academicfreedom/olivierireport.asp>). Another example of a recent study gone amiss is the Gelsinger case. Eighteen year old Jesse Gelsinger died while participating in a gene-transfer trial in the United States. His death led the National Institutes of Health (NIH) to discover many hundreds of unreported adverse events among volunteers enrolled in gene-transfer experiments" (*Gelsinger v. Trustees of the University of Pennsylvania* (Phila. Cnty. Ct. of C.P. filed September 18, 2000), online: Sherman, Silverstein, Holh, Rose and Podolsky Law Offices <http://www.sskrplaw.com/links/healthcare2.html>).

there were intentional releases of radiation into the environment to see the effects on humans. Experiments with plutonium, uranium, and other minerals were conducted, including experiments on prisoners and children. In some cases the people were already sick and were exposed to more radiation, but for experimental rather than therapeutic purposes. A Presidential Commission was established to look into the American federal government's role in the radiation experiments, as the military had played a key role.[46]

The Commission generated three moral principles to serve as the appropriate framework for guiding the ethics of research involving human subjects: respect for persons, beneficence, and justice (the equitable distribution of both the burdens and the benefits of participation in research). These are known as the Belmont principles.[47] The *Belmont Report* consolidated the principles; their traces were evident several decades earlier.

(ii) Council for International Organizations of Medical Sciences Guidelines

The Council for International Organizations of Medical Sciences (CIOMS),[48] in collaboration with the World Health Organization (WHO), has developed the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.[49]

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[46] United States Advisory Committee on Human Radiation Experiments, *Final Report of the Advisory Committee on Human Radiation Experiments* (New York: Oxford University Press, 1996).
[47] *Ibid.* at 104.
[48] CIOMS Guidelines, *supra* note 38:

> The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949. Through its membership, CIOMS is representative of a substantial proportion of the biomedical scientific community. The membership of CIOMS in 2003 includes 48 international member organizations, representing many of the biomedical disciplines, and 18 national members mainly representing national academies of sciences and medical research councils.

[49] *Ibid.*

The initial version was prepared in 1982, and the current version was issued in 2002. The guidelines seek to apply the *Helsinki Declaration* in developing countries.

The International Guidelines apply the three main Belmont ethical principles to biomedical research, that is, research which "includes both medical and behavioral studies pertaining to human health."[50] The Guidelines refer to ethical review committees. Independence of these committees is described as independence from the research team. The Guidelines provide that, if any direct benefit is received by committee members as a result of the research, the benefit should not be contingent on the outcome of the review.

(iii) Professional Codes of Conduct

Some professions have codes of conduct governing professional ethical behavior. These codes developed concurrently with the research ethics policies and guidelines. For example, the American Psychological Association's first Code of Ethics dates back to 1953,[51] and the Canadian Nurses Association's first adoption of such a code was in 1954.[52] These codes prescribe various aspects of professional ethical behavior. The psychologists' Code sets out principles related to research in a detailed fashion, referring to the need for institutional Research Ethics Board approval, consent, client/patient, student, and subordinate research participants, inducements for

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[50] *Helsinki Declaration*, *supra* note 11 at 11.

[51] William T. O'Donohue & Kyle E. Ferguson, *Handbook of Professional Ethics for Psychologists: Issues, Questions, and Controversies* (Thousand Oaks, Cal.: Sage Publications, 2003) at 36. Katz, *supra* note 10, reproduced the 1963 version of the *Ethical Standards of Psychologists*. It outlined ethical principles, starting with an affirmation of human dignity, and following with provisions regarding responsibility, confidentiality, and research precautions, when research involves animals or humans as research subjects. Although it did not refer directly to research ethics committees or boards, it stated with regard to research with humans that investigations using experimental drugs such as hallucinogenic or other drugs "should be conducted only in such settings as clinics, hospitals, or research facilities maintaining appropriate safeguards for the subjects" (at 315).

[52] Canadian Nurses Association, *Everyday Ethics: Putting the Code into Practice* (Ottawa, Ont.: Canadian Nurses Association, 1998) at 6.

participation, debriefing, and related matters. The nurses' Code does not mention research *per se*, but the primary values governing the profession (health and well-being, choice, dignity, confidentiality, fairness, accountability, and practice environments conducive to safe, competent, and ethical care) apply to nurses conducting research. [53] Breaches of the codes can result in professional discipline.

These various influential documents articulate ethical principles to regulate research involving human subjects, and in the case of professional codes of ethics, to regulate professional behavior more generally.

(iv) Other Historical Policies Governing Research

In addition to policies and codes of ethics, social sciences and humanities researchers needed ethics clearance from an ethics committee prior to the *Tri-Council Policy Statement*.[54] The Social Sciences and Humanities Research Council published instructions to this effect to researchers.[55] As well, it appears that in some areas, professors were charged with ensuring that student projects were ethically sound. In some disciplines, there were ethics committees in place which could be consulted on a voluntary basis.[56]

2. *Tri-Council Policy Statement*

Although the historical roots of Research Ethics Boards are found in medicine and health-related disciplines, there has been a fairly recent shift to applying these ethical principles to all research. This shift came about in the early to mid-1990's. The three

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[53] *Ibid.* at 7.
[54] *Supra* note 9.
[55] Social Sciences and Humanities Research Council of Canada, *Ethics Guidelines for Research with Human Subjects* (Ottawa, Ont.: Social Sciences and Humanities Research Council of Canada, Undated (pre-*Tri-Council Policy Statement*)).
[56] Dr. Michael Stingl, Department of Philosophy, University of Lethbridge, *Personal Communication* (20 December 2004).

major Canadian granting councils which are mandated to further research (the Canadian Institutes of Health Research (CIHR), formerly the Medical Research Council (MRC), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC)) decided to collaborate to develop a policy that would apply to researchers across all the disciplines.

The *Tri-Council Policy Statement* was completed in 1998. Bringing the disciplines together under one governance document was a controversial move because research paradigms and approaches among the various disciplines are so different from one another.[57] I will provide further details respecting the *Tri-Council Policy Statement*, particularly as regards Research Ethics Boards, below.

D. What Are Research Ethics Boards?

1. *Definition*

As established by the *Tri-Council Policy Statement* and other rule-sets, respect for human dignity is the overarching principle that Research Ethics Boards apply in making their decisions. Research Ethics Boards are the vehicle through which respect for human dignity is applied in a practical manner.

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[57] Tensions between ethics review of health research on the one hand, and social sciences and humanities research on the other hand, were present when the *Tri-Council Policy Statement* was developed, and continue to the present time. For the most part, social scientists have felt uncomfortable, somewhat like round pegs being forced into square holes. They feel that applying the medical model to qualitative, participatory, or action research is not appropriate. See Social Sciences and Humanities Research Ethics Special Working Committee (Canada), Interagency Advisory Panel on Research Ethics (Canada) & Will C. Van den Hoonaard, *Giving Voice to the Spectrum: Report of the Social Sciences and Humanities Research Ethics Special Working Committee to the Interagency Advisory Panel on Research Ethics* (2004), online: Interagency Advisory Panel & Secretariat on Research Ethics <http://www.pre.ethics.gc.ca/english/workgroups/sshwc/reporttopre.cfm>. See also Raymond De Vries, Debra A. DeBruin & Andrew Goodgame, "Ethics Review of Social, Behavioral, and Economic Research: Where Should we go From Here?" (2004) 14:4 Ethics & Behavior 351; Will C. Van den Hoonaard & Anita Connolly "Anthropological Research in Light of Research-Ethics Review: Canadian Master's Theses, 1995-2004" (2006) 1 Journal of Empirical Research on Human Research Ethics 59.

Research Ethics Boards are one element of a broader system of ethical approval. The system includes other elements, including the following: codes and policies of granting agencies and institutions where research occurs, such as universities; institutional culture, which in the university context, includes collegiality and peer review; research administration (Research Services Office) practices such as withholding research funds until proof of ethical approval is provided (perhaps the most influential and practical element in the enforcement of ethics review rules); and continuing education of researchers.[58]

Taken together, these various elements compose a powerful system which results in researchers conforming to ethical norms.[59] Research Ethics Boards play an important role in this context by examining research protocols for methodological and ethical considerations. Research Ethics Boards ensure that consent forms, and privacy and confidentiality safeguards, where applicable, are in place. They ensure that researchers are sufficiently qualified to conduct the research. For the most part, they are not mandated to monitor the research to ensure that it is being carried out as proposed.

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[58] The education may occur formally when researchers familiarize themselves with the regulations pertaining to their grant applications, or informally by participating in, and following, collegial debates in the Canadian Association of University Teachers (CAUT) Bulletin or other newsletters or electronic list-serves. An example of an electronic list-serve is the National Council on Ethics in Human Research (NCEHR) list-serve, in which interested parties discuss issues of mutual concern in this area (online: NCEHR <http://www.ncehr-cnerh.org/english/listserv.php>).

[59] At least it appears that, on the whole, researchers conform to ethical norms. Monitoring of Research Ethics Board decisions is not conducted in a systematic, evidence-based fashion, so it is difficult to know the actual extent to which researchers behave ethically, and the impacts of research on human subjects. There is a body of literature on monitoring which is beyond the scope of this thesis. For a summary of current forms of monitoring in the health research context, see Section B-2, Principal Investigator Michael McDonald, *The Governance of Health Research Involving Human Subjects (HRIHS)* (Ottawa, Ont.: Law Commission of Canada, 2000), online: W. Maurice Young Centre for Applied Ethics <http://www.ethics.ubc.ca/people/mcdonald/lccmacdonald.pdf> at 71. The issue of monitoring is being examined by the Interagency Advisory Panel on Research Ethics (PRE) as part of the current process of revising the *Tri-Council Policy Statement* (19 January 2006), online: PRE, Government of Canada <http://www.pre.ethics.gc.ca/english/index.cfm>.

Research Ethics Boards have the authority to approve a protocol as submitted, or to require changes or clarifications in methodology, consent forms, or other aspects of the proposed research or investigation. Research Ethics Boards exercise influence in that their decisions determine whether the safeguards for protecting human subjects are adequate.[60] While researchers and granting agencies decide what gets researched, and therefore what is in the public interest to investigate, Research Ethics Boards decide whether the research is methodologically and ethically sound.

Decisions of Research Ethics Boards can allow investigators to proceed with their work in a timely fashion, or can delay their work. The course of researchers' careers is influenced by Research Ethics Board decisions in that a researcher may have been granted funds to conduct research, but Research Ethics Board approval may be required before the investigation can start.[61]

Both the broader system of ethics governance, and Research Ethics Boards in particular, are known to researchers and the academic community, but are largely hidden from the public due to their location within institutional administrative structures. Members of the public who are outside of the academy may not have even heard of research ethics processes, save for occasional stories and interviews carried by the media when research ethics have run amiss.

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[60] Here I am referring to a broad definition of the protection of human subjects. I mean the protection of their persons (as in the case of intrusive medical research), their personal information (which may be anything from health information in the medical context to personal histories in the context of a humanities researcher collecting qualitative data), or anything connected to physical, mental, spiritual, or other types of well-being of individuals.

[61] In some cases, Research Ethics Board approval may have been received earlier in the process, such as at the time of applying for the research grant. Regardless of the sequence of events, however, researchers' careers are impacted by Research Ethics Board decisions because they will only be awarded funding if ethics clearance has been, or will be, obtained. At some institutions, such as the University of Alberta, granting agency funding will not be released to the researcher unless the institution is satisfied that ethics clearance is in place.

2. *Types of Research Ethics Boards*

Research Ethics Boards can be institutional or non-institutional, profession-specific, or community based.

a) Institutional Research Ethics Boards

Perhaps the most common types of Research Ethics Boards are those associated with the institution that created them, and which they serve. These are not-for-profit boards. In the Alberta context, they are boards internal to a University, so are also called academic boards. The Boards associated with the Universities of Alberta and Calgary are conjoint between a health region and a university.

b) Non-Institutional For-Profit Research Ethics Boards

Non-institutional for-profit Research Ethics Boards are commercial boards constituted by for-profit corporations to review their investigation protocols from an ethical point of view. One type is known as "proprietary" boards:

> Proprietary IRBs [Institutional Review Boards] are review boards set up by contract research organizations or by pharmaceutical companies to review research designed to evaluate their own products. Noninstitutional review boards most often are commercial review boards that are set up as profit-making ventures.[62]

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[62] Trudo Lemmons & Alison Thompson, "Noninstitutional Commercial Review Boards in North America" (2001) 23:2 IRB - Ethics & Human Research 1 at 1. Given the inherent conflicts of interest faced by for-profit Research Ethics Boards, there is debate about whether they should be allowed to exist. See Ezekiel J. Emanuel, Trudo Lemmons & C. Elliot, "Should Society Allow Research Ethics Boards to be Run as For-Profit Enterprises?" (2006) 3:7 PLoS Medicine e309, online: <http://www.plosmedicine.org>.

Although there are no for-profit boards based in Alberta, they are relatively common in the rest of Canada. Alberta researchers can use for-profit boards based in other parts of the country.[63]

c) Profession-Specific Research Ethics Boards

An example of a Board specific to a profession is the College of Physicians & Surgeons of Alberta Research Ethics Review Committee (CSPA RERC). The College decided to establish it in 1996; it became operational in 1998. It was created to review proposals of physicians who did not hold academic appointments so did not have access to academic Research Ethics Boards. Before the College's Board was established, physicians "had to rely on privately operated Research Ethics Boards to undertake this review [of research involving human participants]."[64]

Alberta is unique in having such a Board associated with the College of Physicians and Surgeons. This allows the research ethics governance system in Alberta to be stronger and more transparent than in some other jurisdictions.

d) Community Based Research Ethics Boards

In Alberta, the Community Research Ethics Board of Alberta (CREBA) reviews health research that is not covered by other boards. This Board was established by the

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[63] In Alberta, which Research Ethics Board a researcher uses is dependent primarily on the professional association of the researcher. University-affiliated researchers go to their University's board. Physicians not associated with a university go to the Board of the College of Physicians and Surgeons. Researchers associated with the Alberta Cancer Board go to their Board. Community-based researchers who are not affiliated with any of these bodies may go to the Community Research Ethics Board of Alberta (CREBA). A researcher not associated with any of these bodies (for example, someone conducting research for a for-profit company) may use a for-profit board, but this is not very common in Alberta.

[64] College of Physicians & Surgeons of Alberta Research Ethics Review Committee (CSPA RERC), *The Research Ethics Review Committee*, online: CPSA <http://www.cpsa.ab.ca/collegeprograms/attachments/rerc.doc>.

Alberta Heritage Foundation for Medical Research (AHFMR) in 1997. It states its purpose as follows:

> The purpose of CREBA is to prospectively review for ethical acceptability, health research involving people and/or their health information in Alberta. In this role, CREBA fills a gap in the province by providing a forum and process for the review of health research being conducted in any health region, organization or authority that does not already have a duly constituted research ethics review Committee and process.[65]

It is the first community-based Research Ethics Board of its kind in Canada.[66] This speaks well of research ethics in the Alberta context, as Albertans do not have the gap that exists in some other provinces.

The existence of the College's Board and Community Research Ethics Board of Alberta are important aspects of the overall ethics review process in Alberta, which makes the province well-positioned to lead other jurisdictions in good ethics governance practices, particularly in the area of health research.

Ethical guidelines and ethics review processes are starting to emerge from Aboriginal communities as well.[67]

3. *Research Ethics Boards under the* Tri-Council Policy Statement

While no one single piece of legislation or policy regulates all research ethics in Canada, the main national policy is the *Tri-Council Policy Statement*.[68] I will describe

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[65] Alberta Heritage Foundation for Medical Research (AHFMR), *Community Research Ethics Board of Alberta* (2006), online: AHFMR <http://www.ahfmr.ab.ca/creba/background.php>.

[66] *Ibid.*

[67] Michaela Brown, "Research, Respect and Responsibility: A Critical Review of the Tri-Council Policy Statement in Aboriginal Community Based Research" (2005) 3:2 Pimatisiwin: A Journal of Aboriginal and Indigenous Community Health 79 at 81: "Some community organizations, such as the Council of Yukon First Nations (2000), have developed ethical guidelines for outside researchers working in their communities, while other such guidelines have emerged directly from negotiated agreements between partners in collaborate community-outsider projects, such as the Kahnawake Schools Diabetes Prevention Project (1997)." For an example of a First Nations Research Code, see Project for the Protection and Repatriation of First Nation Cultural Heritage in Canada, "'Namgis First Nation Guidelines for Visiting Researchers/Access to Information," online: University of Alberta <http://www.law.ualberta.ca/research/aboriginalculturalheritage/casestudies.htm>.

some *Tri-Council Policy Statement* provisions in terms of which research is covered, and the membership of Research Ethics Boards.

a) Overview of the *Tri-Council Policy Statement* Provisions

The *Tri-Council Policy Statement* defines the type of projects which require review, outlines required membership of Research Ethics Boards, and provides guidance on review procedures and principles to follow,[69] as well as on free and informed consent issues,[70] privacy and confidentiality,[71] and conflict of interest.[72] It addresses specialized areas such as research involving Aboriginal Peoples,[73] clinical trials,[74] human genetic research,[75] research involving human gametes, embryos or feotuses,[76] and human tissue.[77]

Although the *Tri-Council Policy Statement* applies directly to research funded by the three main granting councils (Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council (NSERC), and Social Sciences and Humanities Research Council (SSHRC)), it provides standards for non-grant funded research and is commonly followed regardless of how the research is funded.

b) Membership of Research Ethics Boards

Article 1.3 of the *Tri-Council Policy Statement* provides that Research Ethics Board members, which shall include both men and women, shall consist of:

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[68] *Tri-Council Policy Statement*, *supra* note 9. The common law regime governs the common law provinces; research involving human subjects in Quebec is governed by the *Civil Code of Quebec*, S.Q. 1991, c. 64. In the case of health research, other governing authorities include Health Canada's regulations and, in the case of multi-site American-based clinical trials, the American Federal Regulations apply.
[69] *Tri-Council Policy Statement*, *ibid.*, art. 1.
[70] *Ibid.*, art. 2.
[71] *Ibid.*, art. 3.
[72] *Ibid.*, art. 4.
[73] *Ibid.*, art. 6.
[74] *Ibid.*, art. 7.
[75] *Ibid.*, art. 8.
[76] *Ibid.*, art. 9.
[77] *Ibid.*, art. 10.

> (a) at least two members [who] have broad expertise in the methods or in the areas of research that are covered by the Research Ethics Board;
>
> (b) at least one member [who] is knowledgeable in ethics;
>
> (c) for biomedical research, at least one member [who] is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and
>
> (d) at least one member [who] has no affiliation with the institution, but is recruited from the community served by the institution.[78]

These are minimum requirements. Research Ethics Boards can be, and generally are, larger than the *Tri-Council Policy Statement* requirement of five members and the University of Alberta minimum of six.[79] The *Tri-Council Policy Statement* commentary states that the Research Ethics Board should contain a majority of members whose main responsibilities are research and teaching. It further states that "effective community representation"[80] is essential.

E. Conclusion

I have provided a brief historical overview of Research Ethics Boards. The regulation of research ethics involving human participants grew out of medicine and health related studies, and today applies across all the scholarly disciplines. The foundational principles applied, as reflected in both historic and current regulatory documents, are respect for human dignity, including the autonomy of individuals and gaining consent from people before investigating them, beneficence, nonmaleficience, and justice.

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[78] *Ibid.*, art. 1.3.
[79] *Human Research - University of Alberta Standards for the Protection of Human Research Participants*, General Faculties Council (GFC) Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual>, s. 66.5.3 provides for a minimum of 6 members; *Tri-Council Policy Statement*, *ibid.*, art. 1.3, requires at least five members.
[80] *Tri-Council Policy Statement*, *ibid.*

These principles became operational through the *Nuremberg Code*,[81] which followed directly upon the horrors of the Holocaust. As well, they became operational through the *Helsinki Declaration*,[82] the *Belmont Report*,[83] the Council for International Organizations of Medical Sciences international guidelines (CIOMS), professional codes of conduct, and other documents.

I examined the definition of Research Ethics Boards, placed them in the context of a broader ethics system of review, noted the various types of Research Ethics Boards, and articulated the governing rules of Research Ethics Boards in Canada, focusing particularly on the *Tri-Council Policy Statement*.[84]

In Chapter 2, I will explore the legal principles of independence and impartiality.

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[81] *Supra* note 10.
[82] *Supra* note 11.
[83] *Supra* note 37.
[84] *Supra* note 9.

II. Independence and Impartiality

A. Introduction

In Chapter 1, I examined the historical context and evolution of Research Ethics Boards, defined them, and described the various types of these Boards which are in operation. In Chapter 2, I will explore independence and impartiality. I will examine the legal definitions of independence and impartiality and articulate their governing principles. These principles will provide the context for examining the independence and impartiality of Research Ethics Boards generally, and at the University of Alberta in particular, in Chapter 3.

B. Three Branches of Government

There are three branches of government: the legislature or legislative assembly (the elected body which drafts and passes laws), the executive (the Prime Minister, cabinet, and civil servants in government departments who administer the law through program operation and policy development, as well as the enforcement arm of the state including the military and the police), and the judiciary (judges who interpret laws). These three branches operate at the federal level within Canada, as well as at the provincial level. While the independence and impartiality of the judiciary are a critical means for preserving the rule of law, complete or absolute independence and impartiality are not feasible in practice. Judges must be coordinated with other branches of the state. The executive, legislature, and judiciary do not operate in isolation of one another. The branches of government can be discerned in other organizations as well. In Chapter 3, I will explore the operation of these branches at the University of Alberta.

C. Independence and Impartiality

Independence and impartiality are two distinct but related concepts:

> [J]udicial independence is critical to the public's perception of impartiality. Independence is the cornerstone, a necessary prerequisite, for judicial impartiality.[1]

Judicial independence is a basic foundational tenet of liberal democracy. It is so critical to upholding the rule of law that it has been called the "lifeblood of constitutionalism in democratic societies."[2] Judicial independence supports the rule of law by ensuring that, to the extent humanly possible, decisions are based on the merits of the case rather than on personal biases or whims.

Independence and impartiality exist "for the benefit of the judged, not the judges."[3] Independence and impartiality are important because they allow the public to trust decisions made by decision makers. The public respect and accept the law to a greater extent when independence and impartiality are demonstrably present. Decisions are credible because they are made by people who are unbiased and do not have an interest in the outcome. Public confidence in the judiciary can be maintained. As perception plays a central role in ensuring the fair administration of the judicial system, it is independence and impartiality that allow justice to be seen to be done as well as permitting it to actually be done.

Although there is disagreement about the historical basis of judicial independence,[4] the existence of the principle is doctrinally, constitutionally, and

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[1] *Application under s. 83.28 of the Criminal Code (Re)*, [2004] 2 S.C.R. 248, 2004 SCC 42 at para. 82 [*S. 83.28 Application*]; *R. v. Lippé*, [1991] 2 S.C.R. 114 at 139 [*Lippé*].
[2] *R. v. Beauregard*, [1986] 2 S.C.R. 56 at 70 [*Beauregard*]; *S. 83.28 Application*, *supra* note 1 at para. 70.
[3] *Ell v. Alberta*, [2003] 1 S.C.R. 857, 2003 SCC 35 at para. 29 [*Ell*].
[4] There is a detailed discussion of the historical basis of judicial independence in *Reference Re Remuneration of Judges of the Provincial Court of Prince Edward Island; Reference Re Independence and*

politically well established. As noted in *Ell*,[5] independence preserves public confidence in the judiciary. It allows the law to develop and be properly interpreted and applied according to legal principles rather than political motives. As well, independence preserves the constitution, which establishes a framework and organizational outline by which the tasks involved in establishing and running a government are distributed and accomplished. Independence preserves this constitutional framework.[6]

I will explore the concepts of independence and impartiality by looking briefly at the common law rule against bias and then at the definitions of independence and impartiality in turn. I will not provide an exhaustive account of the independence and impartiality of the judiciary, as that is not the central concern of my thesis. Rather, I will offer an overview of independence and impartiality and explore their elements.

1. *What is Impartiality?*

As I will outline below, Canadian jurisprudence has distinguished between independence and impartiality in recent years. The two concepts still appear as a pair, and this pairing has strong historical roots in British and Canadian common law.

Impartiality of Judges of the Provincial Court of Prince Edward Island, [1997] 3 S.C.R. 3 [*Provincial Judges Reference*]. The Chief Justice concludes that Canada's *Constitution* contains both written and unwritten provisions, and that the preamble of the *Constitution Act of 1867* is the real basis of Canada's commitment to judicial independence. The preamble provides that Canada shall have a constitution similar in principle to that of the United Kingdom, where judicial independence can be traced back to the *Act of Settlement of 1701* (at para. 109). Justice La Forest, in partial dissent, asserts that the structure of Canadian, not British, constitutionalism allows for judicial independence in Canada. He cites the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [*Charter*] and the *Constitution Act, 1867*, as well as constitutional interpretation, as evidence.

[5] *Ell*, *supra* note 3 at paras. 21-23.

[6] Justice Major in the *Ell* decision explains the historical rationale of judicial independence as being threefold: first, the integrity of judicial process making depends on an adjudicative process that is untainted by outside pressures; second, upholding the integrity of the constitutional structure gives rise to the institutional dimension of independence; and third, there is the need to maintain public confidence in the administration of justice (*Ell*, *ibid.*). See also Shimon Shetreet "Judicial Independence: New Conceptual Dimensions and Contemporary Challenges" in Shimon Shetreet & Jules Deschênes, eds., *Judicial Independence: The Contemporary Debate* (Dordrecht, The Netherlands: Martinus Nijhoff Publishers, 1985) 590.

Impartiality is part of the common law principles of natural justice or procedural fairness. Impartiality is so foundational that it is "a condition for the existence of the rule of law, since if judges were not impartial, if they were guided by their biases, prejudgments, and preferences, they would not interpret or apply the law – they would interpret and apply themselves."[7] The maxim, *nemo judex in sua causa debet esse* means that "no one should be the judge in his/her own cause." It is well established that a judge who has a direct interest in the outcome of a case – be it financial or otherwise –is biased and ought not to be hearing the case.[8] It does not matter that the judge is unlikely to actually be influenced by his or her interest. Rather, the problem is that the appearance of justice is missing. A judgment could be fair and impartial in fact, but if a case involves the decision maker's familial or financial interests, an informed and reasonable member of the public could conclude that the decision was not made fairly. It has long been recognized that justice must not only be done, but be seen to be done.[9]

Impartiality also arises in the context of section 11(d) of the *Charter*, which provides that:

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[7] Wayne Renke, "Invoking Independence: Judicial Independence as a No-cut Wage Guarantee" (1994) 5 Points of View 1 at 5.

[8] See *Dimes v. Proprietors of the Grand Junction Canal*, [1852] 3 H.L.C. 759, 10 E.R. 301 [*Dimes* cited to H.L.C.]. In this 19th century case, the Lord Chancellor held shares in a company (some of which were his own shares and others of which he held as trustee for other persons) which was one of the litigants. Given his interest in one of the parties to the suit, his judgment was not allowed to stand.

[9] As Lord Campbell stated in *Dimes*, *ibid.* at 793:

> No one can suppose that Lord Cottenham could be, in the remotest degree, influenced by the interest that he had in this concern; but, my Lords, it is of the last importance that the maxim that no man is to be a judge in his own cause should be held sacred. And that is not to be confined to a cause in which he is a party, but applies to a cause in which he has an interest. Since I have had the honour to be Chief Justice of the Court of Queen's Bench, we have again and again set aside proceedings in inferior tribunals because an individual, who had an interest in a cause, took a part in the decision.... This will be a lesson to all inferior tribunals to take care not only that in their decrees they are not influenced by their personal interest, but to avoid the appearance of labouring under such an influence.

> Any person charged with an offence has the right …
>
> (d) to be presumed innocent until proven guilty according to law in a fair and public hearing by an independent and impartial tribunal.[10]

The s. 11(d) guarantee of impartiality concerns "a state of mind or attitude of the tribunal in relation to the issues and the parties in a particular case."[11] It relates to the need for the "absence of bias, actual or perceived."[12] "Impartial adjudicators … base their decisions on the merits of the case, not the identity of the litigants."[13]

The following terms are synonyms for partiality:

> Bigoted, … discriminatory, favorably disposed, inclined, influenced, … interested, jaundiced, narrow-minded, one-sided, partisan, predisposed, prejudiced, prepossessed, prone, restricted, … subjective, swayed, unbalanced, unequal, uneven, unfair, unjust, unjustified, unreasonable.[14]

Being impartial means being fair and unbiased,[15] relying on the facts of the case at hand to make decisions rather than rendering decisions based on one's beliefs, attitudes, or interests. Impartiality describes the state of mind of a judge or other decision maker.

To understand the state of being unbiased, one must understand bias. Bias is an attitude or approach to decision making which "disqualifies those whom a reasonable person would believe incapable of making a decision impartially."[16] The types of circumstances supporting a reasonable inference of bias or partiality include the following:

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[10] *Charter*, *supra* note 4.
[11] *R. v. Valente*, [1985] 2 S.C.R. 673 at 685 [*Valente*]; *Provincial Judges Reference*, *supra* note 4 at para. 111.
[12] *Provincial Judges Reference*, *ibid.*
[13] *Ibid.* at para. 331. Justice La Forest is dissenting in part, but not on this point.
[14] *R. v. Williams*, [1998] 1 S.C.R. 1128 at para. 9 [*Williams*]. These synonyms for "partial" are quoted from William C. Burton, ed., *Burton's Legal Thesaurus*, 2d ed. (New York: Macmillan Library Reference, 1992) at 374 to illustrate the attitudes that may serve to disqualify a juror.
[15] David J. Mullan, *Administrative Law* (Toronto: Irwin Law, 2001).
[16] *Ibid.* at 542.

a) The judge is in a conflict of interest situation.[17] If a judge would personally benefit or suffer from the outcome, the judge is biased.

b) The judge is biased in the conduct of proceedings because he or she "has an interest in the outcome of the particular matter he or she is called upon to decide."[18] This could be on account of the judge's personal background or the attitudinal bias of a decision-maker, which makes him or her predisposed to a certain outcome.

c) The judge may be biased in the conduct of the proceedings because he or she was involved at an earlier stage of the deliberations, perhaps as the judge in the first instance, or through previous volunteer or paid work which makes it appear "that he or she has already made up his or her mind or is in the position of being able to vindicate a position which he or she had taken earlier."[19]

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[17] Conflicts of interest arise in the context of various professions as well as in discussions of judicial independence. For example, among lawyers, a self-governing profession regulated by the Law Society of Alberta, conflict of interest "is usually employed in the sense of competing client interests; however, a personal interest, loyalty, belief or feeling of a lawyer may also clash with an interest of the client or otherwise interfere with the lawyer's professional judgment" (Law Society of Alberta (LSA), *Code of Professional Conduct* (February 2006), online: LSA <https://www.lawsocietyalberta.com/files/code.pdf> at 6-3). Professor F.C. DeCoste offers an interesting discussion about the independence of lawyers and judges as part of the legal community in *On Coming to Law: An Introduction to Law in Liberal Societies* (Markham, Ont.: Butterworths, 2001) at 49.

[18] Robert W. Macaulay & James L.H. Sprague, *Hearings Before Administrative Tribunals* (Toronto: Carswell, 2002) at 9-20.19 [footnotes omitted].

[19] Macaulay & Sprague, *ibid.* at 9-20.20. See also *Committee for Justice and Liberty v. Canada (National Energy Board)*, [1978] 1 S.C.R. 369 [*Crowe*]. In that case, the decision maker had been involved previously with the case by participating in a study group which influenced setting the question he was adjudicating. A similar principle is articulated in the Law Society of Alberta *Code of Professional Conduct*, *supra* note 17 at 6-2: Lawyers who have served in public office need to be cautious in appearing to act in a compromising situation when they accept employment afterwards.

> [A] lawyer should not accept private employment in a matter in which the lawyer has had a substantial involvement in an adjudicative capacity since it may appear that, in discharging those adjudicative duties, the lawyer was influenced by the prospect of subsequent employment. Similarly, a lawyer should refrain from rendering legal advice on a ruling made by a tribunal of which the lawyer is a member, or was a member at the time the ruling was made.

d) The judge may be biased in the conduct of the proceedings because he or she is "connected to one of the parties or their representatives, or may owe their position or some other debt to them."[20]

e) "[L]egal or practical constraints may have been placed upon a decision-maker that might interfere with his or her ability to decide the matter according to conscience."[21]

f) The judge may be biased due to his or her own stereotyping or assumptions based on categories of people due to race, ethnic or national groupings, gender, or other characteristics. This is known as generic or general prejudice.[22]

g) In a case where strong community sentiments are present, a judge may feel constrained to have his or her judgment reflect the actual or perceived expected outcome rather that the evidence and merits of the case. This is called conformity prejudice.[23]

A judge or other decision maker may be biased without any ill intent or motivation. Simply having a financial or other interest in a case creates an appearance of bias or prejudice, and then impartiality is lacking.

2. *What is Independence?*

a) Definition of Independence

The definition of independence has emerged from the jurisprudence and literature on judicial independence. It refers to:

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[20] Macaulay & Sprague, *ibid.*
[21] *Ibid.*
[22] Neil Vidmar, "Pretrial Prejudice in Canada: A Comparative Perspective on the Criminal Jury" (1996) 79:5 Judicature 249 at 252.
[23] *Ibid.*

> The conditions under which decision makers will be able to make decisions without being in thrall to outside sources (and particularly those who have appointed them) or to other members of staff of the tribunal or agency of which they are members.[24]

The concept of judicial independence is very broad and refers to independence from any external or non-judicial influence, whether political or otherwise:

> "[Judicial independence implies] the complete liberty of individual judges to hear and decide the cases that come before them: no outsider – be it government, pressure group, individual or even another judge – should interfere in fact, or attempt to interfere with the way in which a judge conducts his or her case and makes his or her decision.[25]

In speaking of independence of the judiciary, I mean independence from the other two branches of government, as well as from other persons or groups.

Independence is needed so that judges are not unduly influenced by, or seen to be influenced by, the legislature, the executive, interest groups, and other sources of influence. Judges have to be seen to be doing their job without interference, regardless of the source of the interference. They cannot be seen to be influenced by the media, political partisanship, or other external factors. Judicial decisions must be free from interference from these sources and be based only on the facts of each case.[26]

Additionally, judicial independence demands an absence of interference from business and private sector interests. This issue was addressed in *Lippé*,[27] which considered the independence of provincial Municipal Court Judges who worked part-

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[24] *Supra* note 15 at 544.
[25] *Beauregard, supra* note 2 at 69; *Independence of the Provincial Court of British Columbia Justices of the Peace (Re)*, [2000] 11 W.W.R. 157, 2000 BCSC 1470 [*Provincial Court Justices of the Peace*] at para. 87.
[26] A skeptic may question whether judges are actually free from political bias, since federal appointments in particular are tied to membership in political parties, and membership is accompanied by adherence to particular philosophies or approaches to social issues and questions. Although this is true, and may color the collective flavor of judgments a judge renders, the theory of judicial independence requires that opinions be free from the day to day positions of political parties.
[27] *Lippé, supra* note 1.

time. The question arose as to whether their continuing relationships with clients gave rise to an appearance of bias. "The Court determined that 11(d) was not offended, because the judges' oath of office, code of ethics, and the statutory rules of recusement (disqualification) to avoid conflicts of interest, were sufficient to allay any reasonable apprehension that the judges would be biased."[28]

There are two dimensions of judicial independence: an individual and an institutional or collective dimension.[29] The former concerns a court, judge, or decision maker; the latter refers to a court or tribunal.

D. Independence and Institutional Structure

1. *Independence of Judiciary from Other Two Branches*

a) Three Elements of Judicial Independence

The three elements, or core characteristics, of judicial independence are security of tenure, financial security, and administrative independence. They were identified in the leading case in this area, the Supreme Court of Canada's *Provincial Judges Reference*[30] decision, in which the reduction of judges' salaries in three provinces was at issue.[31]

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[28] Peter W. Hogg, *Constitutional Law of Canada*, stud. ed. (Scarborough, Ont.: Carswell, 2002) at 188.
[29] *Provincial Judges Reference*, *supra* note 4 at para. 118.
[30] *Ibid.*; *Valente*, *supra* note 11; and *Ell*, *supra* note 3 amongst others.
[31] *Provincial Judges Reference*, *ibid.* The provinces were Prince Edward Island, Manitoba, and Alberta. The judgment discussed the proper constitutional roles of the three branches of government, and decided that judges could have their salaries reduced. The context was that other civil servants were undergoing salary cuts in the midst of larger cost saving measures. The Supreme Court held that it was not appropriate for judges' salaries to be dealt with by politicians (the legislative branch) directly; their salaries should not be politicized, lest it appear that their judgments were likewise political. In order to preserve the separation of the three branches of government, the Supreme Court held that there should be a body between the judiciary on the one hand, and the legislative and executive branches of government on the other hand. The Court held that a judicial salary commission, which would make non-binding recommendations regarding the setting of judicial remuneration, was needed.

(i) Security of Tenure

Security of tenure relates to the period and conditions of service of the position held by a judge or other decision maker. Security of tenure is achieved when a decision maker's tenure is free from arbitrary interference by the executive or appointing body.

> The essence of security of tenure for purposes of s. 11(d) is a tenure, whether until an age of retirement, for a fixed term, or for a specific adjudicative task, that is secure against interference by the Executive or other appointing authority in a discretionary or arbitrary manner.[32]

In the case of non-judicial statutory tribunals, the legislator's intention is the primary consideration in deciding whether security of tenure, and the degree of independence in general, is sufficient.[33] As rule-maker, the legislature has discretion to define positions as part-time, full-time, for fixed terms, to be held at pleasure, or to define other variations on that theme.[34] As long as conditions for tenure are not arbitrarily

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[32] *Ell*, *supra* note 3 at para. 32; *Valente*, *supra* note 11 at 698.

[33] Since independence and impartiality requirements exist at common law and constitutionally via the *Charter*, apart from legislation, it is somewhat disturbing to note that it is up to the legislature to decide on the appropriate degree of independence. However, the Supreme Court of Canada clearly holds in *Ocean Port Hotel Ltd. v. British Columbia (General Manager, Liquor Control and Licensing Branch)*, [2001] 2 S.C.R. 781, 2001 SCC 52 [*Ocean Port*] that this is the legislature's proper role. As McLachlin C.J.C. states at para. 24:

> [G]iven [administrative tribunals] primary policy-making function, it is properly the role and responsibility of Parliament and the legislatures to determine the composition and structure required by a tribunal to discharge the responsibilities bestowed upon it. While tribunals may sometimes attract Charter requirements of independence, as a general rule they do not. Thus, the degree of independence required of a particular tribunal is a matter of discerning the intention of Parliament or the legislature and, absent constitutional constraints, this choice must be respected.

At issue in *Ocean Port* was "the degree of independence required of members sitting on administrative tribunals empowered to impose penalties" (at para. 1). The Supreme Court found that the Liquor Appeal Board was "first and foremost a licensing body" (at para. 33).

[34] See *Ocean Port*, *ibid.* The provincial legislature had passed the *Liquor Control and Licensing Act of British Columbia*, R.S.B.C. 1996, c. 267, which provided that the Liquor Appeal Board chair and members "serve at the pleasure of the Lieutenant Governor in Council" and "receive the remuneration set by the Lieutenant Governor in Council" (s. 30(2)(a) & (b), as cited in *Ocean Port*, *ibid.* at para. 15). As the statute's intention was clearly and explicitly stated as creating part-time board positions to be held at the pleasure of the Lieutenant-Governor, the standards of security of tenure for administrative tribunals were met. Although one could have imagined a higher level of security of tenure (for example, by creating full-time, specified term positions), the legislators' intent, which could be clearly discerned, governed.

imposed, the requirements of security of tenure are met.[35]

(ii) Financial Security

Financial security concerns judges' compensation and the process through which their salaries, as well as their pensions and benefits, are determined and adjusted. Financial security encompasses both the individual and institutional dimensions of judicial independence.[36]

Chief Justice Lamer in the *Provincial Judges Reference* case focuses on the institutional dimension. This in turn relates to how the three branches of government relate with one another. The judiciary must not negotiate, in the labor-relations sense of the word, directly with the executive or legislative assemblies, for their salaries. The federal or provincial Crown (the executive) appear before the courts; they cannot be seen to be appearing in court one day and negotiating with the judges for judicial salaries the next. Such a state of affairs would be contrary to judicial independence. Hence, adjustments to judges' salaries must be done through a commission, a body independent of the executive and legislature. Reductions, increases, or freezing of judicial remuneration must go through a special process which is like an "institutional sieve between the judiciary and the other branches of government"[37] to preserve the courts

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[35] See *Ell*, *supra* note 3. In that case, a number of legislative amendments intended to improve the qualifications and independence of Alberta's Justices of the Peace had been made. Some Justices of the Peace who were found to be no longer qualified for their positions argued that they lacked sufficient security of tenure. The Supreme Court of Canada found that the conditions for security of tenure were met, since the interferences were not arbitrary. All Justices of the Peace had to meet specific criteria in terms of education and experience, and those who did not meet the criteria were offered alternate employment.

[36] *Provincial Judges Reference*, *supra* note 4 at para. 121. As well, a principle of financial security is that judges' salaries cannot be reduced to such a level that would undermine public confidence in the independence of the judiciary. "Public confidence in the independence of the judiciary would be undermined if judges were paid at such a low rate that they could be perceived as susceptible to political pressure through economic manipulation, as is witnessed in many countries" (at para. 135).

[37] *Ibid.* at paras. 185 & 189.

from political interference. The entity makes recommendations, which are non-binding, to the executive or legislature.[38]

There is some flexibility with regard to how the independent commissions are structured, but they must meet "the three cardinal requirements of independence, effectiveness and objectivity"[39] to comply with s. 11(d) of the *Charter*. Recommendations of the independent body or commission can be accepted or rejected, but if they are rejected, the decision is subject to review in court based on a simple rationality test.[40] The purpose is to depoliticize the process so that the judges can be seen as making their decisions as a separate body, rather than being directly attached to the other two branches of government.

(iii) Administrative Independence

Administrative independence is the third core characteristic of judicial independence. Of the two dimensions of judicial independence, individual and institutional or collective, administrative independence "only attaches to the court as an institution."[41] It does not apply to individuals.

Matters constituting administrative independence were defined in *Valente* and confirmed in the *Provincial Judges Reference* as "the assignment of judges, sittings of the court and court lists, the allocation of courtrooms, and the direction of administrative

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[38] *Ibid.* at para. 133.
[39] *Ibid.* at para. 185.
[40] The *Provincial Judges Reference*, *ibid.*, case articulated a two-stage analysis describing the test, and the *Provincial Court Judges' Association of New Brunswick v. New Brunswick (Minister of Justice)*, [2005] 2 S.C.R. 286, 2005 SCC 44, reaffirmed the first two stages and added a third one. Accordingly, at para. 31:

> [T]he analysis should be as follows: (1) Has the government articulated a legitimate reason for departing from the commission's recommendations? (2) Do the government's reasons rely upon a reasonable factual foundation? and (3) Viewed globally, has the commission process been respected and have the purposes of the commission – preserving judicial independence and depoliticizing the setting of judicial remuneration – been achieved?

[41] *Provincial Judges Reference*, *ibid.* at para. 120.

staff carrying out these functions."[42] Chief Justice Lamer held that when the Chief Judge in Manitoba lost administrative control of court sittings, this constituted a violation of the administrative independence of the Provincial Court, and of s. 11(d) of the *Charter*.[43]

E. Standard for Assessing Independence and Impartiality

1. *The Test for Independence and Impartiality*

The Supreme Court of Canada, through Lamer C.J.C. in the *Provincial Judges Reference*[44] case, has articulated the applicable test for judicial independence.[45] This is the test under s. 11(d) of the *Charter*.[46]

The test is whether a reasonable and informed person would conclude that the court or tribunal is independent. The informed person has to have thought the matter

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[42] *Ibid.* at para. 260. The issue of sittings of the court arose in Manitoba where the government effectively closed the Provincial Court for certain days and rescheduled trials of remanded accused individuals. Government employees were required to take Fridays in the summer as unpaid days as part of budget reduction measures. One such group of employees was Provincial Court staff. The government (the executive) ordered the withdrawal of court staff for these unpaid days. The executive did this before the Chief Judge announced the closing of the Court on those days. First, the Manitoba Civil Service Commission sent letters to the Crown Attorneys of Manitoba Association, the Legal Aid Lawyers' Association, and the Manitoba Government Employees Union. Then, two weeks later, the Chief Judge advised Provincial Court members that the specified days were reduced work week days and the courts would be closed (*ibid.* at paras. 270-72).

[43] *Ibid.* at para. 270.

[44] *Ibid.*

[45] Numerous cases have referred to the *Provincial Judges Reference* case, but for the most part, they have not changed the decision or the principles for which it stands that I have outlined here. For example, in *Reference Re Same-Sex Marriage*, [2004] 3 S.C.R. 698, 2004 SCC 79, the case was used as authority for a different point, confirming that the Court can refuse to answer reference questions that are "too ambiguous or imprecise to allow an accurate answer" and where insufficient information is provided to answer the question (at para. 63). In *Newfoundland (Treasury Board) v. Newfoundland and Labrador Association of Public and Private Employees (N.A.P.E.)*, [2004] 3 S.C.R. 381, 2004 SCC 66, the *Provincial Judges Reference* case was cited in the context of defining budgetary constraints and budget cuts. In *Chamberlain v. Surrey School District No. 36*, [2002] 4 S.C.R. 710, 2002 SCC 86, the issue was whether a school board made a correct decision with regard to schools using books portraying same-sex families in kindergarten and grade one classrooms. The case was used to note that "insulation of the judicial and political spheres from each other does not only protect our independent judiciary from political interference [but …] It also protects political bodies from excessive interference by the courts" (at para. 205). These cases do not alter the present discussion of judicial independence and impartiality.

[46] The jurisprudence has continued to evolve in the framework of s. 11(d), but Lamer C.J.C. felt it was too limiting a constitutional framework, noting that "the Court is the prisoner of the case which the parties and interveners have presented to us" (*Provincial Judges Reference*, *supra* note 4 at para. 82). If another case were to argue judicial independence in the context of the preamble to the *Constitution Act, 1867*, it could trigger a different set of principles and implications.

through and must view the matter realistically and practically. That reasonable person must have a sense not only of the relevant statutory provisions, but also of their historical context, and the traditions surrounding them. In articulating and affirming this test, Chief Lamer C.J.C. quoted two passages which "correctly establish the standard for the test of reasonable perception for the purposes of s. 11(d)."[47]

The first passage articulating the test states:

> [T]he apprehension of bias must be a reasonable one, held by reasonable and right minded persons, applying themselves to the question and obtaining thereon the required information. In the words of the Court of Appeal, that test is "what would an informed person, viewing the matter realistically and practically – and having thought the matter through – conclude."[48]

That test was adapted in the second passage:

> The question that now has to be determined is whether a reasonable person, who was informed of the relevant statutory provisions, their historical background and the traditions surrounding them, after viewing the matter realistically and practically would conclude [that the tribunal or court was independent].[49]

The test is whether a fully informed reasonable person who is familiar with the case would consider the tribunal to be independent and impartial.

F. A Continuum: Courts to Tribunals

There is a continuum of decision makers, with courts requiring more stringent procedural safeguards than administrative tribunals. In courts, at one end of the spectrum, the rights of persons who are charged with serious offences are protected through high levels of judicial impartiality, as well as processes such as examination, cross-examination, and representation by counsel. At the other end, tribunals with a

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[47] *Provincial Judges Reference*, *ibid.* at para. 113.
[48] *Ibid.*, quoting *Crowe*, *supra* note 19 at 394.
[49] *Provincial Judges Reference*, *ibid.*, quoting *R. v. Valente (No. 2)*, [1983] 41 O.R. (2d) 187 (Ont. C.A.) at para. 51.

policy-making or implementing role have less stringent standards of independence and impartiality.[50]

There are numerous points on the spectrum between courts and tribunals. One example is Justices of the Peace. When the independence of British Columbia Justices of the Peace was at issue, Sigurdson J. acknowledged, "While I recognize that Sitting Justices of the Peace may not be entitled to the same protection as Provincial Court Judges, they do sit as Provincial Court Judges and the nature of the cases that they hear, including Charter issues, require a reasonably high level of protection for institutional judicial independence."[51]

In addition to there being a number of points on the spectrum between courts and administrative tribunals, there are a range of tribunals. They vary among themselves in terms of their processes, sometimes aligning more closely with the executive branch to develop policies and other times acting more like a court. As the Court noted in the *Bell Canada* case:

> Some administrative tribunals are closer to the executive end of the spectrum: their primary purpose is to develop, or supervise the implementation of, particular government policies. *Such tribunals may require little by way of procedural protections.* Other tribunals, however, are closer to the judicial end of the spectrum: their primary purpose is to

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[50] There is a wide range of processes used by administrative tribunals, but both court and tribunal processes are centered around hearing from witnesses. In a civil trial, for example, the typical stages are: the opening statements, examination-in-chief, cross-examination, and closing statements, first by counsel for the plaintiff and then by counsel for the defendant. Typical stages of an administrative agency oral hearing include the applicant presenting his or her case by calling witnesses in turn, who are examined-in-chief by the applicant, cross-examined by the respondent, and re-examined by the applicant. The witness is then subject to clarification questions by the decision maker. When the applicant has presented all his or her witnesses, the respondent follows suit by calling witnesses. Then the applicant and respondent present summaries of their evidence and arguments. These stages are from Macaulay & Sprague, *supra* note 18 at 12-14, as quoted in David W. Elliott, ed., *Administrative Law and Process*, 3d ed. (Concord, Ont.: Captus Press, 2003) at 127.

[51] *Provincial Court Justices of the Peace*, *supra* note 25 at para. 87. Other judicial decisions have also considered the level of independence required of Justices of the Peace. See *Currie v. Ontario (Niagara Escarpment Commission)* (1984), 48 O.R. (2d) 609 (*sub nom. Reference Re Justices of the Peace Act*) 6 O.A.C. 203 (C.A.), as described in *Provincial Court Justices of the Peace*, *ibid.* at para. 44.

> adjudicate disputes through some form of hearing. Tribunals at this end of the spectrum may possess court-like powers and procedures. These powers may bring with them stringent requirements of procedural fairness, including a higher requirement of independence.[52]

The Office of the Information and Privacy Commissioner, for example, is an entity created by statute. The Commissioner maintains an arms length relationship with the government by reporting directly to the legislature on an annual basis (although there is an administrative association with the Department of Government Services). The Commissioner conducts oral and written inquiries, as well as reviews of decisions made by public bodies under the governing legislation. The degree of independence in this model is quite high, in order to protect the public interests of privacy as contemplated by the legislation.

G. Varied Levels of Independence and Impartiality Protections

1. *Introduction*

While courts fall squarely within the judicial branch of government, administrative tribunals are related to both the judiciary and the executive. Administrative tribunals make policy in accordance with their enabling legislation and may have adjudicative roles. Although they are part of the executive branch, their adjudicative function often resembles the activities of the judicial branch. They "span the constitutional divide between the judiciary and the executive."[53] They are different from courts:

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[52] *Bell Canada v. Canadian Telephone Employees Association*, [2003] 1 S.C.R. 884, 2003 SCC 36 at para. 21 [*Bell Canada*] [emphasis added].
[53] *Ocean Port*, *supra* note 33 at para. 32.

> While [administrative tribunals] may possess adjudicative functions, they ultimately operate as part of the executive branch of government, under the mandate of the legislature. They are not courts, and do not occupy the same constitutional role as courts.[54]

It follows, therefore, that as administrative tribunals are not courts, independence and impartiality protections at the same level as the courts' protections are not needed. Although independence and impartiality are not required constitutionally for administrative tribunals,[55] some protections are nonetheless needed as a matter of good policy and best practices. The nature of those protections is dependent on a number of criteria.

2. *Criteria for Assessing the Degree of Protection Necessary*

The level of stringency of protection for independence and impartiality is context specific. The following criteria are relevant to determining the appropriate level of protection for independence and impartiality:

a) the nature of the tribunal,

b) the tribunal's purpose,

c) the interests at stake,

d) the degree of subject-matter expertise required of adjudicators,

e) the scope of the tribunal's jurisdiction,

f) the tribunal's procedures, and

g) oaths of office.

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[54] *Ibid.*
[55] *Ibid.*

a) Nature of the Tribunal

The nature and purpose of the tribunal, and the decision maker's level of responsibility, are closely linked.[56] Generally, the higher the level of responsibility, the greater the degree of protections required. In a British Columbia case, Provincial Court Judges were entitled to a higher level of independence than Sitting Justices of the Peace, but the Justices also sat sometimes as Judges and heard *Charter* issues which "require a reasonably high level of protection of institutional judicial independence."[57]

b) The Tribunal's Purpose

The tribunal's purpose and the nature of its undertakings influence the appropriate level of protection needed for independence and impartiality. Whether the tribunal is mandated to formulate policy is the question here. The greater the policy component, the lower the degree of independence and impartiality protections that are needed.

c) The Interests at Stake

The interests at stake may be considered in light of consequences to the litigants. At their most extreme, the consequences to litigants in criminal cases include, for example, the removal of freedom through being sent to jail. The consequences can also be less severe, such as fines or community service.

These consequences may be contrasted with the consequences of the decision of an administrative tribunal, such as temporarily or permanently losing a business license.

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[56] These two factors, along with others, were cited by Sigurdson J. in *Provincial Court Justices of the Peace*, *supra* note 25 at para. 87: "[C]onstitutional protection for judicial independence is on a continuum and the nature of the required safeguards for judicial independence depends on a number of things including the nature of the tribunal, the interests at stake, whether there is an oath of office and the level of responsibility of the judicial officer."

[57] *Ibid.*

In the *Ocean Port*[58] case, the Liquor Control Board had the authority to remove the hotel owner's license to sell liquor (either temporarily or permanently). Although losing one's livelihood is of considerable consequence, the loss of one's freedom is more severe. The higher the stakes in the decision, the higher the degree of protection required.

d) The Degree of Subject-Matter Expertise Required of Adjudicators

The degree of subject-matter expertise required and the background of adjudicators are critical elements in determining the appropriate levels of protection. In administrative settings, there is often a high degree of complex and specialized knowledge required. In many fields, only a small number of people have expertise, so the factor of collegiality influences the degree of independence and impartiality required as well. The issues in administrative hearings also tend to be highly specialized:

> Most members of regulatory agencies and other public authorities are expected to have special expertise in their field. Not surprisingly, many administrators have had prior experience in the areas they are supposed to regulate as administrators. However, where an administrator is expected to resolve disputes between individual parties, too close a connection with one or more of the parties can create the appearance of bias.[59]

For example, in the *Crowe* case,[60] issues around reasonable apprehension of bias arose because Mr. Crowe had very extensive experience in the field of pipelines and energy before becoming Chair and Chief Executive Officer of the National Energy Board. He had participated in a study group which influenced setting the question he was adjudicating. The majority of the Supreme Court of Canada found that this raised a reasonable apprehension of bias and disqualified him from the panel. They found that

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[58] *Ocean Port*, *supra* note 33.
[59] Elliott, *supra* note 50 at 128.
[60] *Crowe*, *supra* note 19.

there must "be no lack of public confidence in the impartiality of adjudicative agencies ... [which must] ... have regard for the public interest."[61]

The delicate balance that must be reached is in finding adjudicators who are sufficiently knowledgeable about the subject matter and yet not biased (either actually or in perception) in favor of one position or another. Since the principles governing independence and impartiality are based on what a reasonable person would conclude, it is not surprising that there is disagreement on such matters even within the Supreme Court of Canada. The dissenting judges in the *Crowe* case considered it significant that the federal government and a number of provincial governments found no apprehension of bias and were satisfied with Mr. Crowe's appointment. They felt that, based on all the evidence, reasonable and right-minded persons would agree.

With administrative tribunals, independence and impartiality requirements may be relaxed in view of the specialized knowledge required to hear cases and render fair and informed decisions. Judges also have specialized knowledge – they are experts in the governing legal rules rather than being subject-matter experts. They are highly knowledgeable about the rules of court and substantive law. At the Provincial Court level, their knowledge is based on the subject area for which they are responsible, which is determined by the division to which they are assigned, such as criminal, civil, family, juvenile, small claims, or youth. At the Court of Queen's Bench or the Appeal Courts, their knowledge is more general as the types of cases that come to them are more diverse. Judges have access to expert witnesses whose role is to provide the specialized expertise that the court may lack, and to apply it to the particular case. This may be contrasted

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[61] *Ibid.* at 371.

with the expertise of administrative tribunal adjudicators who are very knowledgeable about, for example, the industries to which the legal rules apply.

e) The Scope of the Tribunal's Jurisdiction

The scope of the tribunal's jurisdiction also influences the application of the standards of independence and impartiality which are required. The criminal law, for example, applies to everyone. The public at large is affected by criminal law decisions. Everyone's safety and wellbeing are impacted when laws are enforced. On the other hand, the findings of administrative tribunals interpreting their regulatory legislation, generally apply to defined subsets of the public. Individuals involved and the business or activity is influenced. For example, liquor control rules apply to those who sell and buy liquor. Federal human rights legislation applies to federally regulated employers and providers of goods and services. Although it may be argued that society as a whole benefits when a human rights tribunal rules on the importance of respecting a particular gender or race, for example, typically the direct impacts of the decision are felt by a smaller, more defined group. Canadian Radio and Television Commission (CRTC) regulations apply to broadcasters and related professionals.

The more specific the scope of application, the more specialized the knowledge needed to administer the activities. This point relates back to the high degree of specialization needed to adjudicate regulatory tribunals.

f) The Tribunal's Procedures

The tribunal's procedures are linked to the criteria discussed above. The more the procedure is adversarial or judicial in nature, the greater the need for the independence protections required of judges. Where less adversarial procedures are followed, and

where adjudicators are relying more heavily on their professional knowledge of the industry for context, rather than mainly on witness testimony, independence protections may be relaxed.[62]

g) Oaths of Office

Taking an oath of office is another factor that has been considered to demonstrate the importance and seriousness of holding judicial office. It may be considered along with other factors such as being subject to the Professional Code of Ethics. In *Lippé*,[63] for example, the existence of an oath of office was held to counteract the reasonable apprehension of bias for Municipal Court Judges in Quebec. In that case, acting as a judge part-time, even while practicing law part-time, was found not to create a reasonable apprehension of bias. On the other hand, jury members also take oaths but oaths are not determinative of their impartiality.[64]

My view is that taking an Oath of Office is not the most effective demonstrator of independence and impartiality. It may be likened to Oaths of Confidentiality which some employers such as health care institutions have employees who will be privy to confidential health information sign. I question whether signing such an oath actually prevents breaches of confidentiality.

h) Summary

These various factors, taken together, dictate the level of independence and impartiality required for various bodies. Since independence and impartiality are so important in upholding the rule of law, protecting the administration of justice, and

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[62] See footnote 50, above.
[63] *Lippé*, *supra* note 1.
[64] See *Williams*, *supra* note 14 at para. 25, where challenges to jury members were permitted despite their oaths where the reasonable possibility of prejudice against people of the accused's race was established.

ensuring that public perception of decisions is favorable, one might wonder why lesser protections are acceptable at lower level tribunals.

The courts need more overall stringent protections because the consequences of their decisions are more severe and more broadly applicable to society at large. The highly specialized subject matter of regulatory tribunals and the expertise needed contribute to the relaxation of standards. This is not to minimize the impact of administrative tribunal decisions on individuals or regulatory activities, but rather to acknowledge that the nature of their undertakings is fundamentally different.

The reasonable person would acknowledge that practicality dictates that this is the case. Administrative tribunals are statutorily based, so are mandated to regulate specific industries or tasks. They are policy driven. The high degree of specialization in the interests at stake, the limited scope of the tribunal's jurisdiction, and the fact that decisions apply directly to limited subsets of the population require the high focus of specialized experts. The advanced level of expertise of adjudicators allows independence and impartiality requirements to be relaxed from those of courts.

H. Conclusion

In this chapter I have set out the definitions of judicial independence and impartiality and articulated some of their overall governing principles, noting that they are fundamental requirements of the rule of law. I have explored the justifications of independence and impartiality and articulated the legal test for determining if they are present. I have examined the criteria for assessing the degree of protection necessary and reflected on the continuum of independence and impartiality levels required of administrative tribunals.

In the next chapter I will apply the principles and rules of independence and impartiality to Research Ethics Boards generally and at the University of Alberta specifically.

III. Applying the Principles of Independence and Impartiality to Research Ethics Boards at the University of Alberta

A. Introduction

In Chapter 2, I examined the legal principles of independence and impartiality. I noted that independence arises in the context and constitutional framework of the three branches of government: the legislature (which makes the laws), the executive (which administers and enforces them), and the judiciary (which interprets them by rendering legal judgments on them). Independence arises in the sense that the judiciary must be independent from the legislature and the executive, although there are necessarily points of interdependence and connection among the branches. Impartiality requires that a judge or decision maker be unbiased, that is, make decisions based on the merits of the case rather than his or her own interests. Independence requires that the three elements of security of tenure, financial security, and administrative independence be satisfied.

In this chapter, I will apply the notions of independence and impartiality to the context of Research Ethics Boards at the University of Alberta. Although I am using the University of Alberta as an example, my arguments apply generally to other institutions as well. Like the federal and provincial governments, the University of Alberta has three branches of government. I will describe them, and then examine the structure of Research Ethics Boards at the University of Alberta, noting that the *Tri-Council Policy Statement*[1] requirements have been brought into force on campus under the *University of*

[1] Canadian Institutes of Health Research, National Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2002), online: Public Works and Government Services Canada,

Alberta Standards for the Protection of Human Research Participants as passed by General Faculties Council[2] and the *Post-Secondary Learning Act.*[3] Then I will place Research Ethics Boards on the administrative law continuum of independence and impartiality, following which I will turn to the risks to independence and impartiality Research Ethics Boards face. In particular, I will focus on the threats to organizational independence posed by the current placement of Research Ethics Boards and research administration under the Office of the Vice-President (Research). In Chapter 4, I will explore accreditation as a parallel structure to an independent judicial commission to most effectively address the threats to independence and impartiality. I will assert that accreditation by an arms-length body external to the institution enhances independence and impartiality. Although accreditation involves the application of many objective standards, I will be focusing on the one pertaining to the organizational placement of Research Ethics Boards to support much needed reform in these areas.

As I prepare the foundation to apply the administrative law principles of independence and impartiality to Research Ethics Boards, I note that the application of administrative law principles to the governance of research ethics is a positive and constructive step in other areas as well.[4]

Interagency Panel on Research Ethics <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm> [*Tri-Council Policy Statement*].

[2] *Human Research - University of Alberta Standards for the Protection of Human Research Participants*, General Faculties Council (GFC) Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual>, s. 66 [*GFC Policy s. 66*].

[3] *Post-Secondary Learning Act*, S.A. 2003, c. P-19.5 [*PSLA*].

[4] Michael Hadskis & Peter Carver, "The Long Arm of Administrative Law: Applying Administrative Law Principles to Research Ethics Boards" (2005) 13:2&3 Health L. Rev. 19 at 28 [footnotes omitted]:

> The considerable body of administrative law … can contribute to the [Research Ethics Board] decision-making process in a variety of ways: (1) where the procedural rules contained in the relevant regulatory instruments (e.g., TCPS [Tri-Council Policy Statement], GCP [General Clinical Procedures], and *Clinical Trial Regulations*) are ambiguous or vague, administrative law can clarify the nature of the procedural obligation; (2) where these rules are silent on a procedural matter, administrative law can

B. University of Alberta's Branches of Governance

While the governance structure of governments is determined by the Canadian *Constitution*, the governance framework of the University of Alberta is set forth in the *Post-Secondary Learning Act*. It provides for the offices of the chancellor and senate, as well as the two main governing bodies: the Board of Governors and General Faculties Council. It also sets out the governing provisions of Deans' Council, and faculty and school councils. In addition, the *Act* provides for the appointment of the President and Vice-Presidents by the Board.[5] Vice-Presidents are assigned duties by the Board based on the President's recommendations.[6]

An overview of the three branches of the University of Alberta's governance framework is provided in Figure 1. It is a collegial form of governance, marked by formal and informal consultations among academic and non-academic staff, as well as undergraduate and graduate students.

1. *Legislative Branch*

The legislative branch is the rule-making arm of government. It debates and passes policies. At the University of Alberta, the legislative branch is "bicameral," with the two senior institutional governing bodies being the Board of Governors and General Faculties Council. Under them come the faculty councils and department councils.

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fill the void; (3) where the rules are consistent with administrative law requirements, there is added pressure on [Research Ethics Boards] to obey them; and (4) where the rules are inconsistent, consideration may need to be given to eliminating this inconsistency.

[5] *PSLA*, *supra* note 3, s. 81-82.

[6] *Ibid.*, s. 82(2).

a) Board of Governors

The Board of Governors is composed of the following members: the chair, the chancellor, the president, two university alumni, one member of the university senate, two academic staff members (one nominated by General Faculties Council and the other by the Association of the Academic Staff), two undergraduate students, one graduate student, one non-academic staff member, and up to nine members of the public.[7] The Board of Governors is mandated to "manage and operate [the university] in accordance with its mandate."[8] The Board's powers are wide ranging, and include establishing admission requirements for students,[9] setting tuition fees,[10] disciplining students,[11] acquiring and disposing of land,[12] dealing with financial matters such as borrowing and investing,[13] appointing employees and prescribing their terms and conditions of employment,[14] making bylaws respecting the management of university buildings and land, and parking and traffic bylaws, amongst other matters.[15] These powers must be exercised and carried out "in the best interests of the university."[16]

The interdependence with the executive branch of governance is seen in the legislators' authority to appoint employees and determine their employment conditions. Those employees form the executive branch of governance. The Board's power to discipline students or delegate that function to another body illustrates the interface with the judicial branch. In practice, student discipline is delegated to officials including the

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[7] *Ibid.*, s. 16(3).
[8] *Ibid.*, s. 60(1)(a).
[9] *Ibid.*, s. 60(1)(c).
[10] *Ibid.*, s. 61(1).
[11] *Ibid.*, s. 64.
[12] *Ibid.*, s. 66-67.
[13] *Ibid.*, s. 72-77.
[14] *Ibid.*, s. 83.
[15] *Ibid.*, s. 18 (1) & (2).
[16] *Ibid.*, s. 16(5).

Discipline Officer, Deans, and the Universities Appeals Board. As I shall elaborate below, Research Ethics Boards are primarily judicial in nature.

b) General Faculties Council

General Faculties Council has two types of members: statutory members (those who are members because the *Post-Secondary Learning Act* dictates it) and appointed members. Of the 155 total members, statutory members consist of 27 ex-officio University Officers, 52 faculty, and three students (two from the Students' Union, who are undergraduates, and one from the Graduate Students Association). The appointed members consist of 40 undergraduate students, 12 graduate students, and 21 other appointees.[17] General Faculties Council has broad responsibility for "the academic affairs of the university,"[18] including:

- Courses and programs;
- University Calendar, including the Academic Schedule;
- Conduct and results of examinations;
- Granting and conferring of academic degrees;
- Student appeals;
- Communication with Faculty Councils;
- Library;
- Academic Awards;
- Authorization of School Councils; and
- Recommendations to the Board on affiliation with other institutions, academic planning, campus planning, a building program, the budget, the regulation of residences and dining halls, procedures in respect of appointments, promotions, salaries, tenure and dismissals, and any other matters considered … to be of interest to the university.[19]

Committees form an integral part of the governance structure of the University of Alberta. General Faculties Council has a number of standing committees which are part

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[17] *Ibid.*, s. 23.
[18] *Ibid.*, s. 26(1).
[19] University of Alberta University Secretariat, "Governance 101: University Governance" (April 2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/secretariat/governance101.cfm> at 44 [Governance 101 Materials].

of the legislative branch.[20] It also has constituted appeal boards which are part of the judicial branch, as I will note below in describing that branch.

c) Faculty Councils and Department Councils

Faculty Councils and Department Councils, which have general authority to oversee faculties and departments respectively, also form part of the legislative branch of the university's governance structure. Faculty Councils are provided for in the *Post-Secondary Learning Act*;[21] Department Councils are not mentioned in the *Act* but arise for administrative ease of governance.

2. *Executive Branch*

The executive branch recommends policy to the legislative branch and implements those policies. This branch is composed of University staff, from the President to the Vice-Presidents to the Deans of faculties, Chairs of departments, and Directors of units to faculty, administrative staff, and support staff.[22] This broad range of employees constitutes the executive. The executive may be likened to cabinet and civil servants, who do various jobs at all levels of the bureaucratic hierarchy.

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[20] The standing committees are: Academic Planning Committee (APC), Academic Standards Committee (ASC), Committee on the Learning Environment (CLE), Campus Law Review Committee (CLRC), GFC Executive Committee and Nominating Committee, Facilities Development Committee (FDC), Undergraduate Awards and Scholarship Committee (UASC), and University Teaching Awards Committee (UTAC). An additional GFC entity is the Council on Student Affairs (COSA). Summarized terms of reference for these committees can be found in the Governance 101 Materials, *ibid.* at 49. Full terms of reference can be found at *GFC Standing Committees and Related Bodies: Procedures, Eligibility and General Regulations*, GFC Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual>, s. 60 [*GFC Standing Committees*].

[21] *PSLA*, *supra* note 3, s. 28-29.

[22] Most executive members are governed by a collective agreement. The Association of the Academic Staff: University of Alberta (AAS:UA) oversees collective agreements for Faculty, Administrative, and Professional Officers, Faculty Service Officers, Librarians, and Sessionals (see AAS:UA, online: University of Alberta <http://www.uofaweb.ualberta.ca/aasua/index.cfm>). The Non-Academic Staff Association (NASA) represents a wide diversity of support staff in areas including business, administration, finance, technical positions, maintenance, and the trades (see NASA, online: University of Alberta <http://www.nasa.ualberta.ca/>).

3. *Judicial Branch*

The judicial branch "sits in judgment on individual cases independent of [the] Legislative or Executive branch [and] acts in accord with judicial policies passed by Legislative branch."[23] It is regulated by General Faculties Council for students via the academic standing provisions in the General Faculties Council Policy Manual,[24] the *Code of Student Behaviour*,[25] and the policy regarding practicum placements.[26] For academic and non-academic staff, the judicial function is regulated by Universities policies, such as the Research and Scholarship Integrity Policy,[27] and the respective collective agreements.[28]

The judicial branch includes the General Appeals Committee (GAC)[29] which is established under the Faculty collective agreement. Additional student appeal boards are the University Appeal Board (UAB), Academic Appeals Committee (AAC), and the Practice Review Board (PRB), which report annually to the General Faculties Council.[30]

4. *Placing Research Ethics Boards in the University's Governance Structures*

Research Ethics Boards are part of the judicial branch of the University of Alberta's governance structure. They are judicial in the sense that they make decisions

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[23] Governance 101 Materials, *supra* note 19 at 13.
[24] *GFC Academic Standing*, GFC Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual>, s. 7.
[25] *Code of Student Behaviour*, GFC Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual>, s. 30.
[26] *Practicum Placements, Professional Practice and the Public Interest*, GFC Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual>, s. 87.
[27] *University of Alberta Research and Scholarship Integrity Policy*, GFC Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual>, s. 96.2.
[28] Governance 101 Materials, *supra* note 19 at 13.
[29] *General Appeals Committee (GAC)*, GFC Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual>, s. 56.
[30] Summarized terms of reference for the Academic Appeals Committee (AAC), University Appeal Board (UAB), and Practice Review Board (PRB) can be found in Governance 101 Materials, *supra* note 19 at 51. Full terms of reference can be found at *GFC Standing Committees*, *supra* note 20.

about cases. They adjudicate the merits of research ethics protocols to determine, from an ethical and methodological perspective, whether the research should proceed. They are judicial in nature in that they weigh and accept or reject the research protocols submitted to them (generally they accept them, either as submitted or, as is frequently the case, after changes are made).

Research Ethics Boards do not have a legislative branch component. They are not attached to Department Councils, Faculty Councils, General Faculties Council, or the Board. They are not rule-making entities but, like the courts, they may develop interpretations and approaches to rules, and apply them using the doctrine of precedent.

Research Ethics Boards, while primarily judicial in nature, have executive components. In addition to their judicial function of assessing protocols and granting ethical clearance, they perform the executive function of drafting standards to guide their work (to ensure the protection of human research participants within the context of the *Tri-Council Policy Statement* and *GFC Policy Section 66*), and developing and implementing procedures for review of the protocols.[31] Research Ethics Board Chairs, along with research administration officials from the Human Research Protections Office, develop "administrative" policies and procedures. These are not General Faculties Council policies but rather are operational strategies and directions.

The executive responsibility of creating and implementing institutional policies pertaining to research ethics falls primarily to the Human Research Protections Office at the University of Alberta (or to broadly representative stakeholder groups and granting

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[31] See for example, University of Alberta Arts, Science and Law Research Ethics Board (ASL REB), *Terms of Reference* (2002), online: University of Alberta <http://www.uofaweb.ualberta.ca/arts/nav04.cfm?nav04=18888&nav03=18639&nav02=18632&nav01=18539>.

councils, amongst others, in the case of national policies). Responsibility for enacting policies is reserved to General Faculties Council.

C. The Legal Status of Research Ethics Boards

Research Ethics Boards are not, generally speaking, separate legal entities (although a for-profit one might be established as a corporation, which is a type of legal entity). They are not statutorily established decision-making bodies. That is, unlike the Canadian Human Rights Commission, for example, which was created by the *Canadian Human Rights Act*,[32] Research Ethics Boards do not exist because a statute has created them. Their members are not public servants, or other government officials.

Research Ethics Boards at University of Alberta derive their legal authority indirectly from the *Post-Secondary Learning Act* which gives General Faculties Council responsibility for academic affairs of the University.[33] Although governing academic affairs is a complex and multi-faceted undertaking, one aspect relates to overseeing research, and one type of research involves using humans as subjects. *GFC Policy s. 66* sets out the provisions for Research Ethics Boards,[34] as the University must comply with the *Tri-Council Policy Statement*.

In addition, the University of Alberta – Health Research Ethics Board derives some legal authority from the *Health Information Act*[35] as well. The Health Research Ethics Board existed before the *Health Information Act* was passed in 2001; at that time it

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[32] *Canadian Human Rights Act*, R.S.C. 1985, c. H-6.
[33] *PSLA*, *supra* note 3, s. 26(1).
[34] *Supra* note 2. Another policy that is also significant in this context at the University of Alberta: *Conflict of Commitment and Conflict of Interest Policy*, GFC Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual/content.cfm?ID_page=37638>, s. 35 [*Conflict of Interest Policy*] and the *University of Alberta Research and Scholarship Integrity Policy*, *supra* note 27. As noted in Chapter 1, there are also other governing documents such as the *Health Information Act*, R.S.A. 2000, c. H-5 [*HIA*], Health Canada Provisions, and the American Regulations.
[35] *HIA*, *ibid.*

was named in the *Health Information Act Designation Regulation* as one of six boards in Alberta designated to follow specified provisions of the *Health Information Act* about disclosing personally identifying health information for research purposes, the role of research ethics boards in assessing consent, privacy safeguards, and related matters.[36]

1. *Judicial Review of Research Ethics Boards Decisions*

Related to the issue of legal status of Research Ethics Boards is the question of whether their decisions can be judicially reviewed. Although detailed discussions of judicial review, the requisites for administrative law remedies, and the availability of judicial review given potential remedies under collective agreements are beyond the scope of the current discussion, it is reasonable to conclude that Research Ethics Board processes could be the subject of a non-collective agreement based judicial review.[37] For example, an unsatisfied researcher whose time-sensitive research is being delayed by a Research Ethics Board could seek judicial review in the nature of *mandamus*. This would likely occur only in exceptional circumstances, as he or she would have recourse to the Academic Staff Association collective agreement and, potentially, the grievance process. Normally, internal recourses would be exhausted before seeking judicial review. However, if the case went to the court system, the researcher could argue that the delay or

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[36] The other five designated Research Ethics Boards are: the Alberta Cancer Board – Research Ethics Committee; the College of Physicians and Surgeons of Alberta – Research Ethics Review Committee (CPSA RERC); the Alberta Heritage Foundation for Medical Research – Community Health Ethics Research Review Committee (CREBA); the University of Calgary – Conjoint Health Research Ethics Board; and the University of Lethbridge – Human Subject Research Committee (*Health Information Act Designation Regulation, Alta. Reg.*, 69/2001 s. 2). There is a further statutory connection for CREBA, as it is a committee established by the Alberta Heritage Foundation for Medical Research pursuant to s. 19(1) of the *Alberta Heritage Foundation for Medical Research Act,* R.S.A. 2000, c. A-21. See also Chapter 1, "*Tri-Council Policy Statement*," above.

[37] Professors Hadskis and Carver have noted that *certiorari* or other remedies may be available in the context of Research Ethics Boards decisions: Hadskis & Carver, *supra* note 4 at 27. For a detailed discussion of administrative law remedies, see David J. Mullan & J.M. Evans, *Administrative Law: Cases, Text, and Materials*, 5th ed. (Toronto: Emond Montgomery, 2003) at 1087-187, and David Phillip Jones and Anne S. de Villars, *Principles of Administrative Law*, 3d ed. (Scarborough, Ont.: Carswell, 1999) at 523-708.

denial of ethical clearance to conduct research amounted to an infringement of academic freedom, perhaps as an aspect of the rights of free speech protected under s. 2(b) of the *Charter*.

A research subject who was harmed by research approved by the Board could also bring a civil suit against the Research Ethics Board. The civil liability of Research Ethics Boards was canvassed in the Canadian case of *Weiss c. Solomon*[38] and the American case of *Grimes v. Kennedy Krieger Institute, Inc.*[39]

D. Research Ethics Boards on the Administrative Law Spectrum

In Chapter 2, I described a continuum of independence and impartiality. I used the example of criminal courts as a place where stringent procedural safeguards for independence are in place to represent one end of the spectrum. Administrative tribunals fall at the other end of the spectrum. Research Ethics Boards would be placed closer to the administrative than the judicial pole of the spectrum.

1. *Applying the Criteria for Assessing the Degree of Protection Necessary*

In Chapter 2, I discussed some criteria which determine how stringently the standards of independence and impartiality apply to various bodies. Now I will apply those criteria to Research Ethics Boards.

a) Nature of the Tribunal

On one level, institutional Research Ethics Boards in the academic context are merely one of many University committees, one which happens to be dedicated to

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[38] *Weiss c. Solomon*, [1989] R.J.Q. 731.

[39] *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807 (Md. 2001) [*Grimes*]. See Daniel L. Icenogle, "IRBs, Conflict and Liability: Will We See IRBs in Court? Or is it When?" (2002) 1:1 Clinical Medicine & Research 63; Hazel Glenn Beh, "The Role of Institutional Review Boards in Protecting Human Subjects: Are We Really Ready to Fix a Broken System?" (2002) 26 Law & Psych. Rev. 1.

promoting research, the byproduct of which is that the University is allowed to access federal research and other sources of funding. These Boards may be perceived by some as bureaucratic obstacles to conducting research, one more hoop to jump through before research funding is released to researchers who are keen to proceed with their investigations.

However, I view Research Ethics Boards as unique and particularly significant in that they are entrusted with a fiduciary-like duty to attend to the well-being of others. These others are human subjects (also called research participants) who, whether healthy or in states of compromised health, are in vulnerable positions due to the power differentials between themselves and the researchers. They are being invited to participate in studies such as sociological questionnaires, education based surveys, medical trials, drug studies, and other investigations which may involve recollecting traumatic personal events, revealing sensitive information, or submitting to medical interventions. Risks to privacy and confidentiality arise, as do other risks and harms. Both qualitative and quantitative studies are conducted by a broad range of researchers from the social sciences and humanities to the scientific and medical fields. Research Ethics Boards are tasked with ensuring that the human dignity of subjects is preserved and that research subjects are dealt with respectfully and appropriately.

Generally, higher levels of responsibility require greater levels of independence and impartiality protections. Given the nature of Research Ethics Boards as protectors of the well-being of others, a reasonably high level of independence and impartiality should be afforded these bodies.

b) The Tribunal's Purpose

The mechanism through which Research Ethics Boards protect human subjects is by providing ethical clearance of research protocols, including consent forms, and related documentation. This is a considerable level of responsibility, tending toward the judicial end of the independence and impartiality protections.

Where the policy formulation component is great, fewer independence and impartiality protections are required. Research Ethics Boards fall mid-way here; they do not develop formal institutional policies, but they do devise procedures and administrative rules through which to carry out their mandate. For example, they may decide that students conducting research via personal interviews in private homes should attend in pairs for safety reasons.

c) The Interests at Stake

Analyzing consequences to litigants is the traditional way of assessing the interests at stake, with the most severe consequences requiring the highest degrees of independence and impartiality protection.

The interests at stake in criminal cases may result in a jail sentence. In an administrative law case, such as *Ocean Port*,[40] the result may be the temporary cancellation of a license to sell liquor. With Research Ethics Boards, there are no litigants in the sense of parties with opposing interests; rather, there are researchers who bring their protocols forward. There may be opposing interests if research goals conflict with the protection of human subjects.

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[40] *Ocean Port Hotel Ltd. v. British Columbia (General Manager, Liquor Control and Licensing Branch)*, [2001] 2 S.C.R. 781, 2001 SCC 52.

The main interest at stake is the protection of human subjects. Closely related to this interest is the well-being of the public at large, which needs to be assured that research is conducted in a fair and equitable fashion. Another interest is the rights of researchers to conduct research, thereby gaining a livelihood and contributing to the body of generalizable knowledge. Yet another interest at stake is that of the University in its reputation as an institution mandated to attract research funds and make discoveries which add to the body of research knowledge. The ability of journals to attract and publish articles is another interest at stake. Although all of the interests need to be balanced, the protection of human subjects has priority as an interest.[41] On balance, the interests at stake warrant a higher degree of protection, nearer the judicial than the administrative side. In the most extreme cases, inadequately protecting human subjects could, in the case of cancer drug trials or radiation and chemotherapy for example, result in death to the participants.

d) The Degree of Subject-Matter Expertise Required of Adjudicators

A very high degree of subject matter expertise is needed by Research Ethics Board members. The protocols reviewed are highly specialized by discipline. Methodologies are best understood by someone with the same background. It is a process of peer review.

The high degree of specialization required of Research Ethics Board members (excepting the community representative) is more akin to administrative hearings than judicial proceedings. The delicate balance in administrative hearings of needing people

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[41] This is in accordance with the World Medical Association General Assembly, *Declaration of Helsinki* (2004), online: WMA <http://www.wma.net/e/policy/b3.htm>, and other documents discussed in Chapter 1, above.

who are well versed in the subject area but not in a conflict of interest position suggests more of an administrative than judicial level of independence and impartiality.

e) The Scope of the Tribunal's Jurisdiction

The scope of the rules and who is impacted by the decisions are closely related. As noted above, Research Ethics Boards are entrusted with protecting the well-being of others. A Research Ethics Board is different from a hiring committee which decides who to hire for a position, or a Faculty Evaluation Committee which decides who should be promoted, or a graduate student selection committee which decides which students to admit. While these committees make decisions that impact deeply on the lives of those involved, the people directly impacted are part of the process and can speak for themselves, ask questions, and enlist formal or informal advocates such as staff or student associations to speak on their behalf. With Research Ethics Boards, the voice of human subjects is intended to be heard through public representatives, but whether those voices are adequately represented and heard at the table is debatable.[42]

In some types of research, such as medical research, the interests at stake may be great. When cancer researchers uncover drug or prevention discoveries, for example, the public at large is impacted in an important direct and positive way. This enlarges the population which is affected by the Research Ethics Board's decisions. In effect, this increases the scope of the rules in question as well.

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[42] Patricia E. Bauer, "A Few Simple Truths about your Community IRB Members" (2001) 23:1 IRB: Ethics & Human Research 7 at 7: "In the alphabet-soup world of the highly credentialed, the input of these singleton community members is easily overlooked – or, worse, discounted. Does this power imbalance make for credible research review? Not really." Richard S. Saver, "What IRBs Could Learn from Corporate Boards" (2005) 27:5 IRB: Ethics & Human Research 1 at 1 [footnotes omitted]: "[O]nly a token number of nonaffiliated members serve on most IRBs. Nonaffiliated members can easily find their concerns dismissed or marginalized, and they report having frequent negative experiences in interacting with institutional researchers on the IRB." See also Ernest Wallwork, "Failed Community Representation: Does the Process Inhibit Full IRB Participation by Community Representatives?" (Fall 2003), online: Protecting Human Subjects <http://www.science.doe.gov/ober/humsubj/> at 4.

The scope of the rules, while impacting the public as a whole, is most directly applicable to human subjects. This is an identifiable, narrow, well-defined group, akin to a group directly impacted by human rights legislation or radio and television regulation professionals. This specific scope of application suggests an administrative or regulatory level of independence and impartiality protections.

f) The Tribunal's Procedures

Research Ethics Board procedures do not resemble judicial proceedings in that they are not adversarial. The researcher, unlike a criminal accused or parties to a civil case, is not normally present at the proceedings.

At Research Ethics Boards meetings, one or two main reviewers who work in the same discipline as the researcher present a summary of the protocol to the other Board members, along with a recommendation of what the Board's decision should be. Board members discuss the protocol and approve or do not approve it. They can ask for further clarification if necessary. They can also impose conditions on their approval.

g) Oaths of Office

Research Ethics Board members do not take an oath of office. The presence or absence of an oath would not appear to be an effective indicator of appropriate independence and impartiality levels.

h) Summary

Some factors suggest that Research Ethics Boards fall toward the administrative end of the spectrum and others suggest a more judicial inclination. Given that the consequences of decisions of Research Ethics Boards are so far-reaching, and have the

potential to do great harm or great good, the independence and impartiality rules should be applied in a manner mid-way between administrative tribunals and courts.

E. Risks to Independence and Impartiality

1. *General Risks*

Before turning to the risks to independence and impartiality in the context of organizational placement of Research Ethics Boards, I will briefly explore the question of more general risks to the current governance system of research ethics. It is a somewhat difficult area to explore because records of Research Ethics Boards decisions are not public; it is not an "open" system like the court system where most, or most parts of, decisions are published and available for scrutiny. However, the recent American experience, where human subjects have been hurt as a result of participating in research, have led to reforms across the border from which Canada can learn.[43]

Another type of overall risk relates to pressures of commercialization in the academy.[44] These pressures relate not only to the academy as a whole, but to research as well.[45] Research collaborations between the academy and industry should also be closely monitored for ethics considerations.[46]

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[43] In the *Grimes* case, *supra* note 38, children were exposed to lead poisoning in housing during the course of research. Ethics approval had been granted. This case, amongst others, prompted reforms to the American regulation of research involving human subjects. See Beh, *supra* note 38. Another example is the case of Ellen Roche, a 24 year old healthy research volunteer who died after participating in research involving inhaling an unapproved drug. Beh, *ibid.* at 27, canvassed the surrounding circumstances of research related deaths of Ellen Roche and Jesse Gelsinger. Cherry explores problematic American cases of human research subjects from the point of view of financial conflicts of interest (Mark J. Cherry, "Financial Conflicts of Interest and the Human Passion to Innovate" in Ana Smith Iltis, ed., *Research Ethics* (New York: Routledge, 2006) 147).

[44] See James L. Turk, ed., *The Corporate Campus: Commercialization and the Dangers to Canada's Colleges and Universities* (Toronto: James Lorimer and Company Ltd., 2000), Jennifer Washburn, *University, Inc.* (New York: Perseus Books, 2005); Canadian Association of University Teachers (CAUT), "Issues and Campaigns – Opposing Commercialization," online: CAUT <http://www.caut.ca/en/issues/commercialization/default.asp>.

[45] For example, see Timothy Caulfield, "Sustainability and the Balancing of the Health Care and Innovation Agendas: The Commercialization of Genetic Research" (2003) 66 Sask. L. Rev. 629; Catherine D.

An additional risk is rooted in conflicts of interest. The *Tri-Council Policy Statement* provides that researchers and Research Ethics Boards members "shall disclose actual, perceived or potential conflicts of interest" to the Research Ethics Board, which "should develop mechanisms to address and resolve" them.[47] The University of Alberta *GFC Policy s. 66* repeats this statement and adds by way of introduction: "[R]esearchers hold trust relationships with research participants, research sponsors, institutions, professional bodies, and society. These trust relationships can be put at risk by conflicts of interest that may compromise independence, objectivity, or ethical duties."[48]

The *Tri-Council Policy Statement* clearly intends that Research Ethics Boards should act independently from the institution, but is silent on how that should be implemented. With regard to institutional conflicts of interest, it provides:

> The REB must act independently from the parent organization. Therefore, institutions must respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties. Situations may arise where the parent organization has a strong interest in seeing a project approved before all ethical questions are resolved. As the body mandated to maintain high ethical standards, however, the public trust and integrity of the research process require that the REB maintain an arms-length relationship with the parent organization and avoid and manage real or apparent conflicts of interest.[49]

DeAngelis, "The Influence of Money on Medical Science" (2006) 296 Journal of the American Medical Association E1, online: JAMA <http: jama.ama-assn.org/cgi/content/full/296.8.jed60051v1>. For an argument refuting the commonly expressed view of commercialization being negative and interests conflicted, see Thomas P. Stossel, "Regulating Academic-Industrial Research Relationships – Solving Problems or Stifling Progress?" (2005) 353:10 New England Journal of Medicine 1060.

[46] Jennifer L. Gold, Michell S. Laxer & Paula A. Rochon, "Monitoring Contracts with Industry: Why Research Ethics Boards Must be Involved" (2003) 11 Health L. Rev. 13. Regarding the disclosure of personal interests in commercialization by physician-researchers, see *Moore v. Regents of the University of California*, 793 P. 2d (Cal. 1990), cert. denied, 499 U.S. 936 (1991).

[47] *Tri-Council Policy Statement*, *supra* note 1 at 4.1. See also *Conflict of Interest Policy*, *supra* note 34.

[48] *GFC Policy s.* 66, *supra* note 2, s. 66.11.

[49] *Tri-Council Policy Statement*, *supra* note 1 at 4.2.

2. *Risks Specific to Independence and Impartiality*

The test for independence is whether a reasonable informed person who has thought the matter through and is viewing it realistically and practically would conclude that the court or tribunal is independent.

Risks to independence may attach to the three elements, or core characteristics, of judicial independence: security of tenure, financial security, and administrative independence. Judicial independence has two dimensions: individual and institutional or collective. The third core characteristic, administrative independence, "only attaches to the court as an institution"[50] and does not apply to individuals. Risks to impartiality reveal themselves in the presence of actual or perceived bias or conflict of interest.

The independence and impartiality risks that I am concerned about pertain primarily to structural or organizational independence, that is, they relate to Research Ethics Boards as an institution. I will focus on the threats that arise from the inappropriate placement of Research Ethics Boards in the institution's organizational structure. The institutional independence problem is that ethics review is too closely linked to the Office of the Vice-President (Research), the office mandated to bring research funds into the university.

3. *Organizational Place of Research Ethics Boards*

At the University of Alberta, as is typically the case with Canadian universities, the oversight of Research Ethics Boards falls under the jurisdiction of the Vice-President (Research)'s office. As that office provides support and services for conducting research,

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[50] *Reference Re Remuneration of Judges of the Provincial Court of Prince Edward Island; Reference Re Independence and Impartiality of Judges of the Provincial Court of Prince Edward Island; R. v. Campbell; R. v. Ekmecic; R. v. Wickman; Manitoba Provincial Judges Association v. Manitoba*, [1997] 3 S.C.R. 3 at para. 120.

it appears on its face to be an appropriate place. However, as it is mandated to bring research funds into the University, it lacks an appearance of objectivity. It lacks the necessary arms-length relationship from Research Ethics Boards.

In the context of courts, judges note how the administration of justice is brought into disrepute when independence and impartiality are compromised. In the Research Ethics Board context, the parallel risk is that the public perception of researchers is compromised.

a) University of Alberta Research Ethics Boards

(i) Current Structure

As part of a large, research intensive university, the University of Alberta's Research Ethics Board framework consists of a series of nine Research Ethics Boards which serve all 18 faculties and schools.[51] Sometimes Research Ethics Boards are dedicated to a single faculty, other times they are combined to serve several faculties. For example, the Faculty of Education has its own Research Ethics Board; the Faculties of Arts, Science, and Law are served by a single one. The health-related faculties have two panels, one to review biomedical protocols from clinical investigators, and another which reviews health protocols.

There is also a standing committee of the Vice-President (Research), the University Committee on Human Research Ethics (UCHRE). Research Ethics Boards report to their Faculty Deans and to the Office of the Vice-President (Research) through this committee.[52] The committee also makes policy recommendations to the Vice-

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[51] *About Research Ethics Boards (REBs)* (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/orca/nav02.cfm?nav02=48774&nav01=21675>.
[52] *GFC Policy s. 66*, *supra* note 2, s. 66.5.1.

President (Research) and receives appeals from faculty level committees.[53] There are normally very few, if any, appeals from Research Ethics Board decisions. This is because, as noted above, protocols generally get approved either as submitted or following revisions requested by Research Ethics Boards.[54]

(ii) Current Organizational Placement

Research at the University of Alberta comes under the jurisdiction of the Office of the Vice-President (Research). First I will place the Office of the Vice-President (Research) in the context of the other senior executives, and then I will describe the structure of governance of Research Ethics Boards.

The Senior Executive Responsibility Structure is mapped out in Figure 2. The Board of Governors is the highest governing body of the University. The President reports to the Board, and the Provost reports to the President. There are five Vice-Presidents, of which the Vice-President (Research) is one, and they report to the President, as shown by a solid line on the organizational chart. The organizational chart also shows a dotted line to the Provost, which "signifies Provost's operational responsibility for coordinating portfolios' initiatives and implementing strategic/budget/policy decisions of Board and President."[55] The Provost is considered to be the "first among equals" or *primus inter pares.*

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[53] *Ibid.*, s. 66.7.

[54] The details of when Research Ethics Board approval is needed, and from whom, are contained in a presentation entitled "Human Research Protections Orientation" by Dr. Michael Enzle (online: Human Research Protections Office <http://www.uofaweb.ualberta.ca/vpresearch/pdf/OrgChartVP(Research).pdf>).

[55] "Senior Executive Responsibility Structure, University of Alberta – Current," Organizational Chart (Figure 2).

The institutional governance structure of Research Ethics Boards is diagramed in Figure 3. The Office of the Vice-President (Research) has four units reporting to it,[56] one of which is the Senior Associate Vice-President (Research), to whom two offices report: the Research Services Office (RSO) which helps researchers at various stages of research, from finding funding to ensuring links with faculty specific resources,[57] and the Office of Research Certifications and Approvals (ORCA).[58] The Research Services Office will only administer a grant if ethics approval has been granted. While policies and procedures are important, the Research Services Office plays a critical and powerful role in having the ability to withhold grant funds if there is not proof of ethics approval.

The Office of Research Certifications and Approvals is composed of the Human Research Protections Office (HRPO) which regulates the ethical use of human subjects in research and serves as the executive branch for Research Ethics Boards, and the University Veterinarian, whose office oversees animal welfare and regulates research involving animals.

There are also faculty-based Research Facilitation Offices (RFOs) which are extensions of the central Research Services Office.[59] The Research Facilitation Initiative was undertaken in response to the dramatic increase in the volume of research at the University of Alberta in recent years. Although not all the research involves human subjects, the sheer volume stands as a stark reminder of the need to have appropriate and

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[56] The units are: Senior Associate Vice-President (Research), Associate Vice-President (Research), Technology, Entrepreneur & Company Edmonton (TEC), and Special Advisor.
[57] University of Alberta Research Services Office, online: <http://www.rso.ualberta.ca>.
[58] Office of Research Certifications and Approvals (ORCA), online: University of Alberta <http://www.uofaweb.ualberta.ca/orca/>. The Office of Research Certifications and Approvals was created by the University of Alberta to ensure Tri-Council Memorandum of Understanding compliance regarding research involving human subjects or animals.
[59] *Supra* note 56.

efficient processes in place to deal with the research administration.[60] The Research Facilitation Initiative, which is considered a best practice, included hiring ten Research Facilitators and approximately 25 support staff to deal with research administration.

4. *Problems with the Current Structure*

a) Impartiality

(i) Organizational Placement of Research Ethics Boards

The problem with the current organizational structure at the University of Alberta is that it would not meet accreditation standards. One criterion for accreditation would be that the organizational placement of the research administration office (the Human Research Protection Office) would not result in a perception of partiality.

The current placement of the research administration office would fail to meet this criterion because a perception of partiality is caused when the Office of the Vice-President is seen to have both the protection of human research subjects and obtaining research funds under its jurisdiction. The reasonable person who is aware of the facts would question how a portfolio aiming to attract as many research dollars as possible to the institution could concurrently serve to protect the best interests of human subjects. The reasonable person would ask how two masters could be served at the same time. That person would fear that financial gain and political considerations in obtaining grants and supporting as many research endeavors as possible would take precedence.

Further, the reasonable person would observe that Research Ethics Board members are aware that research and publication are critical to the career advancement of

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[60] Vice-President (Research), *Research Administration Roles and Responsibilities Procedures* (2006), online: University of Alberta <http://www.rso.ualberta.ca/roles.cfm>.

themselves and their colleagues. Regarded from this perspective, the peer review process may be likened to foxes guarding the henhouse.

These fears would inform the reasonable person's perceptions, and perceptions are critical, as justice must not only be done, but be seen to be done as well. The reasonable person would conclude that impartiality is compromised.

As I explained in Chapter 2, bias is introduced when a judge or decision maker is influenced, or perceived to be influenced, in decision making by factors other than the merits of the case. The problem with the University's current structure is that research ethics administrative governance and Research Ethics Boards appear to be making decisions on protocols based on the desire to bring more research money into the institution rather than on the merits of the case. It does not matter that the University of Alberta's organizational structure is common to that of many other Canadian universities. The fact that a practice is widespread does not mean that it most effectively protects perceptions of impartiality.

When the University of British Columbia recently experienced problems with research ethics, one of the investigatory team's recommendations was to change the organizational structure so that the Research Ethics Board would report directly to the Vice-President (Research). Previously, it had reported to the Office of Research Services. The shift in reporting was recommended in order "to avoid even the appearance of a conflict of interest, as well as to enhance the prestige and credibility"[61] of the Board. While this recommendation was a step in the right direction in terms of the protection of the perception of impartiality, it did not go far enough. In Chapter 4, I will

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[61] T. Douglas Kinsella & Edward W. Keyserlingk, *Review of the Clinical Ethics Research Board – The University of British Columbia: Final Report* (1 August 2001) [unpublished, archived at University of British Columbia] at 4.

elaborate on a shift in organizational placement which would have research ethics administration reporting directly to the President.

(ii) Bias and Collegial Relationships

A problem regarding both impartiality and independence concerns pressures Research Ethics Boards members could feel to approve the research of colleagues. The member could be reluctant to oppose or question the colleague's research, since the member's own research will be submitted to the same Research Ethics Board in due course, and could receive a similar reception.[62]

The role of protecting human research subjects suggests a need to reflect soberly on proposed research; the role of attracting research dollars implies an urgency in proceeding with the research. The juxtaposition of these two opposing roles is troubling. As health lawyer Jocelyn Downie has stated:

> [Research Ethics Board] members are often appointed and renewed by or at the direction or recommendation of the institution's Vice President of Research – an individual with a mandate to promote research. He or she is frequently judged by the number of projects and the amount of research money flowing into the institution. It is certainly the case that at least some Vice Presidents of Research have attempted to shape their institutions' [Research Ethics Boards] in ways that promote research (e.g., not renewing members and Chairs who "cause trouble" or not appointing members and Chairs who they think will "cause trouble"). While many Offices of Research Services and Vice Presidents of Research do place the protection of research subjects above the promotion of research, some do

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[62] The complexities involved in bias and collegial relationships are illustrated in the February 2006 terminations of two editors of the Canadian Medical Association Journal (CMAJ). The issues concerned editorial autonomy and independence in the context of disagreements about, *inter alia*, whether a controversial article on *Plan B* (night-after contraception pills) would be published. Pharmacists were alleged to be collecting sexual practice histories, without ethical approval, of women buying the *Plan B* pills. One of the numerous issues that emerged was whether this was journalism or scientific research. See Mark H. Wilson, "The CMA's Legitimation Crisis" (2006) 332 British Medical Journal 854; Miriam Shuchman & Donald A. Redelmeier, "Politics and Independence – The Collapse of the *Canadian Medical Association Journal*" (2006) 354 New England Medical Journal 1337; Canadian Medical Association Journal, "Editorial: The editorial autonomy of CMAJ" (2006) 174 Canadian Medical Association Journal 9; Peter A. Singer & Gordon H Guyatt, "Deeper Lessons from the CMAJ Debacle" (2006) 367 Lancet 1551; Jerome P. Kassirer *et al.*, "Commentary: Editorial Autonomy of CMAJ" (2006) 174:7 Canadian Medical Association Journal 945.

> not (or do not do so consistently). All of these sorts of conflicts of interest at the [Research Ethics Board] level threaten the independence of ethics review and, thereby, threaten the capacity of the current system to protect research subjects.[63]

b) Independence

I will deal with each of the three core characteristics of independence as they relate to the University of Alberta in turn.

(i) Security of Tenure

Security of tenure refers to whether a judge is appointed full-time or part-time, and under what conditions. It includes whether the appointment is for an ongoing (non time limited) term, a specified term such as two or three years, or can be terminated at the pleasure of the appointing body.

In the University of Alberta context, there are two groups in relation to which "tenure" issues arise. The first is the Human Research Protections Office. These staff are University employees and can be appointed permanently or for specified terms. Collective agreement provisions would apply unless they occupy excluded positions. The second group, members of Research Ethics Boards, has their employment governed by the main position they occupy, since serving on the Research Ethics Board is an additional duty that constitutes part of their community service. The reasonable person would conclude that these arrangements do not compromise independence.

The *Tri-Council Policy Statement*[64] and the *University of Alberta Standards for the Protection of Human Research Participants*[65] provide guidance on membership of Research Ethics Boards, but not specifically on appointments. In practice, some

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[63] Jocelyn Downie, "Contemporary Health Research: A Cautionary Tale" (2003) Special Edition Health L.J. 1 at 12.
[64] *Tri-Council Policy Statement, supra* note 1.
[65] *GFC Policy s. 66, supra* note 2.

appointments are statutory, that is, they are based on administrative positions held, such being an Associate Dean. Others are selected on an ad hoc basis in view of research expertise, availability, willingness to serve, or related factors.

There is not a clear relationship between academic tenure and "tenure" on Research Ethics Boards. Generally, members serve a specified term and then it is renewed or considered complete. Positions with academic tenure, on the other hand, are held in members' respective faculties.

(ii) Financial Security

Financial security refers to how judges are paid – the source and amount of their salaries and benefits, and whether the executive's role is appropriately independent so that it does not appear that the executive is unduly influencing the judiciary. In the University of Alberta context, the staff of the Human Research Protections Office are members of the executive who are paid by the University via the Office of the Vice-President (Research), and are protected by collective agreements. The reasonable person would find this problematic from an independence perspective, in the same way as it is of concern from the point of view of impartiality.

Secondly, there are Research Ethics Boards members, most of whom are employed on campus and paid by the University through the budgets of their appointing faculty or department. Research Ethics Board members with academic appointments offer their time as community service, which is one of the grounds on which tenure is granted. This service is acknowledged in annual performance evaluations.

A reasonable person would observe that Research Ethics Boards members, acting in judicial capacities, report to and are evaluated by the executive. These arrangements are suspect from an independence perspective.

Normally appointments to Research Ethics Boards are made to tenured rather than non-tenured academics.

(iii) Administrative Independence

As noted above, administrative independence concerns the head of the judiciary retaining administrative control over such matters as assigning cases, timing and location of court sittings, and related functions.

At the University of Alberta the reasonable person would not have reason to question administrative control of Research Ethics Boards sittings. The Boards set their own meeting times, places, agendas, and processes for conducting ethical reviews. These arrangements do not compromise the independence and impartiality of the Boards.

Administrative independence is particularly important in the context of the protection of human subjects because Research Ethics Boards are entrusted to care for the well-being of people used in research, who are often in vulnerable positions.

F. Conclusion

In this Chapter I have applied the principles of independence and impartiality to Research Ethics Boards at the University of Alberta and identified risks which would be decreased by reforms. In Chapter 4, I will propose reforms.

IV. Recommendations for Reform

A. Introduction

The rule of law requires an independent judiciary. In applying the principles of independence and impartiality to Research Ethics Boards and research ethics administration at the University of Alberta, I identified some risks to the independence and impartiality of these Boards. In Chapter 4, I will elaborate on these risks and propose reforms which will enhance the independence and impartiality of Research Ethics Boards.

The Supreme Court of Canada has held that having an arms-length body that deals with sensitive matters separating the executive and legislative branches from the judiciary enhances the independence of the judiciary. In the *Provincial Judges Reference*[1] case, this arose in the context of protecting financial security, where the sensitive matter was judicial remuneration. It was held that an independent commission was needed to make recommendations on whether to freeze, increase, or decrease judicial salaries and benefits. The commission made recommendations to the executive or legislature so that the judiciary was not seen to be negotiating directly with the other branches of government. The presence of the independent commission enhances the independence of the judiciary.

In the case of Research Ethics Boards, the sensitive matter is not remuneration, but rather the governance of the Boards. The risk created by the absence of a body which is arms-length from the institution (that is, from both the executive members in research

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[1] *Reference Re Remuneration of Judges of the Provincial Court of Prince Edward Island; Reference Re Independence and Impartiality of Judges of the Provincial Court of Prince Edward Island; R. v. Campbell; R. v. Ekmecic; R. v. Wickman; Manitoba Provincial Judges Association v. Manitoba*, [1997] 3 S.C.R. 3 [*Provincial Judges Reference*].

ethics administration and the judicial members serving on Research Ethics Boards). I will argue in favor of accreditation, and submit that the accrediting body should perform a parallel function to the judicial commission, certifying that the Board has policies and procedures in place to fulfill its *Tri-Council Policy Statement*[2] and institutional policy obligations.

Accreditation would have a number of standards or criteria which the institution being accredited would have to meet, such as meeting training requirements and ensuring appropriate Board composition or membership. The criterion of particular interest to me is the organizational placement of research ethics administration and Research Ethics Boards. Their current placement under the Office of the Vice-President (Research) compromises the appearance of impartiality. The organizational placement of Research Ethics Boards in too close proximity to the Office of the Vice-President (Research) gives rise to actual or perceived conflicts of interest since the Office of the Vice-President (Research) is mandated both to attract research funds and protect the integrity of human subjects used in research.

In exploring reforms which will enhance the independence and impartiality of Research Ethics Boards, first I will address the impracticalities of a complete overhaul of ethics governance processes, and rule out the alternative of removing the Boards entirely from the institution to obtain the most "pure" sense of independence. Then I will observe that oversight of ethics governance by the courts, while a useful back-up mechanism, is not in itself sufficient to adequately protect human subjects.

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[2] Canadian Institutes of Health Research, National Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2002), online: Public Works and Government Services Canada, Interagency Panel on Research Ethics <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm> [*Tri-Council Policy Statement*].

I will argue that the best solution is to institute a national system of accreditation of Research Ethics Boards. I will define accreditation, and demonstrate that accreditation processes meet the three cardinal characteristics of arms-length judicial commissions – independence, effectiveness, and objectivity.

1. *Complete Overhaul Impractical*

It may be argued that a complete overhaul of Research Ethics Boards processes is needed. I am sympathetic to this point of view, but the scope of my thesis does not extend to broad reforms of the entire process. Ideally, in the future, a complete overhaul of the system would result in human subjects being better protected than they are at the present time. Other characteristics of such an overhaul would be that the solutions found would be practical to implement and would increase accountability and transparency of Research Ethics Boards to the University community as well as the public at large. The completely reformed system would take into account the fact that Research Ethics Boards are currently overburdened with work[3] and perceived by some investigators as inefficient, arbitrary, inconsistent, and lacking in perspective.[4]

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[3] Regarding the overburdening of work of Research Ethics Boards, sociologist Brenda Beagan has observed in the Canadian context that:

> [T]he need for an infusion of resources cannot be overstated. At the various sites across the country the story is the same: overburdened REB members are stretched to the breaking point. These are well-intentioned volunteers doing the best they can to address extraordinarily complex issues under severe time constraints with severely limited resources. As the work becomes increasingly complicated with globalization, technology and commercialization, REBs are struggling to find committee chairs or even members. (Brenda L. Beagan, "Ethics Review for Human Subjects Research: Interviews with Members of Research Ethics Boards and National Organizations" in M. McDonald, ed., *The Governance of Health Research Involving Human Subjects (HRIHS)* (Ottawa, Ont.: Law Commission of Canada, 2000) 173 at 229.)

The situation is similar in Europe, where one commentator states that "[t]he Ethics Committees too often lack the necessary resources to fulfill their task adequately" (D. Sprumont, "Legal Protection of Human Research Subjects" (1999) 6 Eur. J. Health L. 25 at 31). Recent changes to the Australian system of ethics governance have prompted an Ethics Committee Chair to observe that the vast workload increase of

Ideally, a complete overhaul of ethics governance would streamline the work of Research Ethics Boards and make it less administratively burdensome.[5] Protocols would be processed more quickly and efficiently, thus resulting in researchers being able to proceed with research in a more timely fashion and Research Ethics Boards members being less stressed with the ever increasing volume of reviews. Although these issues are real and pressing, the reforms I am proposing do not deal with all of these ongoing complex and important issues, but rather address some discreet issues related to enhancing independence and impartiality of Research Ethics Boards.

Health lawyer Jocelyn Downie has argued that we should "make Research Ethics Boards truly independent" and that "we need to explore taking Research Ethics Boards out of the institutions conducting the research."[6] While the notion of "true independence" is a laudable one with which I agree philosophically, I believe it would be impractical and difficult to implement. What would "true independence" mean, particularly with regard to funding, office space, support staff, appointment of members, and relationship with the research community?

The purest form of independence would mean that the Research Ethics Boards, Research Services Offices, Human Research Protection Offices, and other affiliated units would not receive any funding, office space, or support staff from the University. The

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Human Research Ethics Committees (HRECs) has caused them significant strain (Susan Dodds, "Is the Australian HREC System Sustainable?" (2002) 21:3 Monash Bioethics Review 43).

[4] Elizabeth Hohmann & Jonathan Woodson, "'Inefficient, Arbitrary, Inconsistent' A Frank Look at how some Investigators View IRBs and a Few Suggestions for Improvement" (2005) 12 Protecting Human Subjects 12.

[5] Casarett *et al.*, have observed that the research ethics process is bureaucratic, cumbersome, and leads to delays in receiving ethics clearance: D. Casarett, E. Fox & J.A. Tulsky, *Recommendations for the Ethical Conduct of Quality Improvement* (Washington, D.C.: National Center for Ethics in Health Care, Veterans Health Administration, 2002); D. Casarett, J.H.T. Karlawish & J. Sugarman, "Determining when Quality Improvement Initiatives should be Considered Research: Proposed Criteria and Potential Implications" (2000) 283:17 Journal of the American Medical Association 2275.

[6] Jocelyn Downie, "Contemporary Health Research: A Cautionary Tale" (2003) Special Edition Health L.J. 1 at 16.

University would not have any direct or indirect control over the appointment of Research Ethics Board members. However, under the *Tri-Council Policy Statement*,[7] the University would still be responsible for ensuring that the conditions of funding from the Councils, one of which is ethical clearance, were met. The University would still need to demonstrate compliance with its own internal policies and procedures, which have to be consistent with the *Tri-Council Policy Statement*. As well, the University would be responsible from a liability perspective, and would be justifiably concerned about injury to human subjects and damage to the University's reputation should problems arise.

In addition, if Research Ethics Boards were taken entirely out of the institution, they would nevertheless need funding, office space, and support staff. The University's funding from the three Councils is dependent on following the *Tri-Council Policy Statement*, and the University has a considerable amount to retain and gain in both dollars and reputation as a research intensive institution by remaining compliant. The University would, therefore, appropriately insist on having input into the appointment or election of Research Ethics Board chairs and members. This, in turn, would re-jeopardize the Board's independence.

The research community would, appropriately, expect administrative convenience in dealing with the Boards, which may well be compromised by removing them from the institution. There are also less quantifiable issues of respect toward, and acceptance of, Research Ethics Boards by the research community. Although the current arrangements are flawed, at least part of what allows these Boards to work to the extent that they do, is the "collegial" link with the rest of the University. In other words, there is some credibility earned by Research Ethics Board members who are known to their

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[7] *Supra* note 2.

colleagues, the researchers, as fair and equitable individuals. In saying this, I acknowledge that the opposite may also be true: a colleague known to be a "difficult" person may lack credibility as a Research Ethics Board member, however, that person's influence can be balanced against the presence of others on the Board. Issues around collegiality are related to the need for judicial independence in that justice must be seen to be done as well as be done. That is, the collegial relations of Research Ethics Board members imply a respect for the process of ethical clearance.

Therefore, it is not practical or consistent with independence principles to remove Research Ethics Boards from the institution completely. Research Ethics Boards need some institutional support and affiliation; however, they should not be so closely linked to the Office of the Vice-President (Research) whose interests are conflicted in terms of both needing to attract research funds and operate through a bureaucratic orientation on the one hand and ensure protection of human subjects through ethical review on the other. Research Ethics Boards need to be located differently within the institution, and be more accountable to the University community and the broader community.

2. *Oversight by Courts Insufficient*

There is currently some potential oversight of research ethics governance by the courts, at least in theory. If a research subject were harmed as a result of participating in the research, he or she could sue the various parties involved, one set of which could be the Research Ethics Board members.[8] In practice, however, thousands of research ethics protocols are reviewed annually in Canada, but cases have rarely arisen. Brief judicial

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[8] For a detailed consideration of issues regarding Research Ethics Board liability for negligence, see Jennifer L. Gold, "Watching the Watchdogs: Negligence, Liability, and Research Ethics Boards" (2003) 11 Health L.J. 153.

mention has been made of the duty of medical researchers with regard to consent.[9] The liability and role of Research Ethics Boards were explored by a lower Quebec court in *Weiss c. Solomon*[10] and by the Maryland Court of Appeals in *Grimes v. Kennedy Krieger Institute, Inc.*[11] The landmark case of *Grimes* adopted the *Nuremberg Code* as a legal source of research ethics principles, independent of federal statutory law. Many human subjects are not in a financial position to litigate, and even if finances were not at issue, not all would have sufficient knowledge or inclination to sue.

Judicial review is also likely available to researchers who believe their research is being unfairly delayed or denied by Research Ethics Boards. Normally, however, such disputes are resolved within the institution, having recourse to the academic staff association and applicable collective agreement if necessary.

B. Accreditation

I will argue in favor of a model for research ethics governance in which the accrediting body for Research Ethics Boards acts as an independent body which affirms the institution's practical and operational commitment to the *Tri-Council Policy Statement*[12] and institutional ethics policies. The external accrediting body would operate at a national level, at arms length from the internal branches of institutional government.

This model is based on the independent judicial commission model articulated by the Supreme Court of Canada in the *Provincial Judges Reference* case.[13] In that case, financial security of the judiciary was at issue. The concept of an external body placed

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[9] *Halushka v. University of Saskatchewan et al.*, (1965) 53 D.L.R. (2d) 436 (Sask. C.A.).
[10] *Weiss c. Solomon*, [1989] R.J.Q. 731.
[11] *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807 (Md. 2001) [*Grimes*]. Hazel Glenn Beh, "The Role of Institutional Review Boards in Protecting Human Subjects: Are We Really Ready to Fix a Broken System?" (2002) 26 Law & Psychol. Rev. 1 at 19.
[12] *Supra* note 2.
[13] *Supra* note 1.

between the judiciary and the other branches of government is a useful and practical one which I am adopting.

The Supreme Court of Canada likened the independent commission to an "institutional sieve between the judiciary and the other branches of government"[14] to preserve the courts from political and other interference. The commissions make highly persuasive, although not binding, recommendations to the executive and legislature. The Supreme Court of Canada held that the judicial commission mechanism to determine salaries and benefits had to satisfy the three cardinal requirements of being independent, effective, and objective.[15]

First I will define accreditation, and then I will explain how the accrediting body and the process of accreditation meet each of the cardinal principles of being independent, effective, and objective. I will demonstrate that a formal system of accreditation of Research Ethics Boards would enhance impartiality, independence, and credibility of these Boards. Accreditation would provide objective standards by which Boards can operate.

1. *What is Accreditation?*

In recent years, there has been considerable discussion in Canada about the possibility of adopting an accreditation framework for Research Ethics Boards.

The Task Force for the Development of an Accreditation System for Human Research Protection Programs National Council on Ethics in Human Research (NCEHR) released a report in July 2006 recommending that an accreditation system be developed

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[14] *Ibid.* at paras. 185 & 189.
[15] *Ibid.* at para. 185.

and accepted in Canada.[16] Accreditation has already been instituted in the United Kingdom[17] and partly instituted in the United States.[18] Arguments in favor of instituting an accreditation system for Australian Human Research Ethics Committees have also been made.[19]

Having an accreditation process allows a body which is arms-length from the institution to formally recognize that the institution's Research Ethics Boards uniformly meet specific, measurable standards. Accreditation is well known in medical arenas such as hospitals, health regions, and university-based training programs:[20]

> Accreditation is based on continuously evolving standards derived from guidelines, regulations, policies and best practices. It is a self-assessment and peer-assessment process used by organizations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the system.[21]

Accreditation is a voluntary and objective process conducted by people who are independent of the organization being accredited:

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[16] National Council on Ethics in Human Research (NCEHR), Task Force for the Development of an Accreditation System for Human Research Protection Programs, *Promoting Ethical Research with Humans: Report of the Task Force for the Development of an Accreditation System for Human Research Protection Programs* (July 2006), online: NCEHR <http://www.ncehr-cnerh.org/english/Task%20Force%20Report_FINAL_18%20July%202006.pdf > [NCEHR Report 2006]. See also Henry Dinsdale, "Professional Responsibility and the Protection of Human Subjects of Research in Canada" (2005) 13:2&3 Health L. Rev. 80.

[17] S. Kerrison & A.M. Pollock, "The Reform of UK Research Ethics Committees: Throwing the Baby Out With the Bath Water?" (2005) 31 Journal of Medical Ethics 487.

[18] In the United States, there are "2 voluntary accreditation processes, and 1 mandatory accreditation process limited to Veterans Affairs (VA) medical centers": Ezekiel J. Emanuel *et al.*, "Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals" (2004) 141 Annals of Internal Medicine 282 at 286.

[19] Some Australian commentators argue that existing accreditation structures for health care facilities should be used to assess health research governance structures as well. See Michael K. Walsh, John J. McNeil & Kerry J. Breen, "Improving the Governance of Health Research" (2005) 182:9 Medical Journal of Australia 468.

[20] Health service organizations undergo accreditation every three years by the Canadian Council on Health Services Accreditation (CCHSA), online: CCHSA <http://www.cchsa.ca/>. Laboratories such as those in the Cross Cancer Institute in Edmonton are also accredited through the College of Physicians and Surgeons of Alberta (CPSA). The College also offers accreditation in areas related to Diagnostic Imaging, Hemodialysis, as well as other areas (online: CPSA <http://www.cpsa.ab.ca/aboutus/qoc_dept.asp>).

[21] National Council on Ethics in Human Research, Report of the NCEHR Task Force to Study Models of Accreditation for Human Research Protection Programs in Canada (29 March 2002) as quoted in NCEHR Report 2006, *supra* note 16 at 25.

> A successful accreditation program is voluntary (a frequently misunderstood and underestimated element), involves peers, incorporates lay persons, is educational, rigorously evaluative, has buy-in by major stakeholders and is accountable to the public and adheres to internationally agreed methods of accreditation. It is done by an organization at arm's length from the program/organization being accredited.[22]

The accreditation model being recommended by the National Council on Ethics in Human Research would result in the accreditation of institutions. It would not require that every Research Ethics Board at the University of Alberta undergo a separate accreditation process. Rather, the institution as a whole would be assessed.

There are financial costs involved in the accreditation of Research Ethics Boards. The Task Force considered various models in 2005 including fee for service, funding from government, funding from a consortium of stakeholders, and a blend of the options.[23] The NCEHR Report 2006 contemplated institutions requesting accreditation paying for it in due course, once the program is up and running.

In an accreditation process a team of experts from outside the institution measures the institution based on various criteria, such as:

- how the protection of human subjects is ensured;
- whether processes for handling protocols (including, importantly, processes for asking questions of researchers and requesting changes to protocols prior to approval) are efficient and streamlined;
- whether Research Ethics Board members receive sufficient and consistent training (the training would be on substantive ethics issues as well as policies governing research integrity and conflict of interest); and
- whether appointments are made in a clear and transparent way that ensures an appropriate balance of subject matter expertise and community representation.

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[22] Dinsdale, *supra* note 16 at 81.
[23] NCEHR Report 2006, *supra* note 16 at 93.

It has been noted that "[t]he process of accreditation, with a strong educational component, will reduce the incidents of problematic practices by promoting a culture of ethical conduct of research and ensuring that researchers and administrators are familiar with and adhere to the policies and regulations governing research."[24]

The accreditation process would be heavily focused on education and would consist of a site visit preceded by a significant amount of self-study by the institution being accredited. Education of the institution about ethics issues would be distinguished from training of Research Ethics Boards members, with education being more broadly focused.

The prospect of accrediting Research Ethics Boards has been met with mixed reviews. Generally, the medical community accepts it as a useful measure while acknowledging that the process would require significant preparation time, and that time would be asked of already stretched resources. The acceptance may be due to their already being familiar with accreditation processes. University programs of study, hospitals, and health care regions all go through accreditation processes at regular intervals, normally every three years. Working in this environment leads to acceptance of the process.

While some scholars from the Social Sciences and the Humanities accept accreditation of ethics governance processes as a constructive measure,[25] others feel more skeptical. Although the literature has yet to develop on the subject, some researchers in

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[24] *Ibid.* at 21.

[25] Margorie A. Speers, "Human Research Protection Programs Accreditation and Oversight – Can it Help With Your IRB?" (July 2004) 18:7 Psychological Science Agenda, online: American Psychological Association <http://www.apa.org/science/psa/jul4aahrpprt.html>; Margorie A. Speers, "Accreditation Helps Researchers and Subjects Alike" (May 2003) 16:5 Observer, online: Association for Psychological Science <http://www.psychologicalscience.org/observer/getArticle.cfm?id=1280>.

the social sciences perceive that accreditation will introduce more bureaucracy into an already bureaucratic process. These social scientists resist the process, worrying that a lot of time, effort, and money will be spent to fix problems that do not exist. As noted above, there is already skepticism among researchers from the social sciences and humanities regarding the dominance of the medical model of ethics review.[26]

The judicial commission model I am using requires that the external body be independent, effective, and objective.

a) Independent

The accrediting body would be attached to NCEHR and be external to the institution being accredited. This brings a critical level of independence to the process.

On the other hand, given the small size of the research community across Canada, it would be difficult to find a completely independent accrediting team to visit any given institution, as colleagues are known to one another. Nonetheless, representing NCEHR and having specified standards to apply add to the independence of the process.

One might worry that NCEHR and the accreditors could be subconsciously motivated by self-interest to continue to have work, resulting in the development of the accreditation process, and then the accreditation process itself, becoming overly bureaucratic. I acknowledge that there have been numerous studies and task forces already, which have resulted in additional consultations, voluminous submissions, and more studies and reports. I appreciate that this gives the appearance of generating more and more work for the Canadian research ethics community, and NCEHR, the eventual accreditors. While stakeholder consultations and the careful review of competing

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[26] See Chapter 1, footnote 57.

interests are important, a balance must be struck in which the benefits to human subjects are not overshadowed by bureaucratic processes.

In the final analysis, the absence of an external body to undertake accreditation means that there is no objective way to assess whether the University of Alberta is meeting its obligations under the *Tri-Council Policy Statement*[27] and University policies consistently, both in terms of consistency of decision making among the various Research Ethics Boards and in terms of other institutions as well.

b) Effective

A reasonable person familiar with the circumstances would find it acceptable that measurable evidence of effectiveness will be gathered over time. The potential for finding such evidence is strong in terms of accreditation increasing transparency and accountability of Research Ethics Boards. As well, the NCEHR Report 2006 builds a quality assurance mechanism to assess the effectiveness of accreditation into its recommendations.[28] Effectiveness also reveals itself in terms of consistency of process and reciprocity.

(i) Consistency

There would be a greater likelihood of consistency of decisions among University of Alberta boards as well as among boards of other institutions. This predictability would enable researchers to have a better sense of what to expect in the ethics review process. Consistency of decisions improves the appearance of impartiality. It appears more that decisions are being made based on the merits of the case if there are objective criteria to follow in assessing the protocols.

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[27] *Supra* note 2.
[28] NCEHR Report 2006, *supra* note 16.

(ii) Reciprocity

One aspect of efficiency is reciprocity. If all the major research institutions in Canada were accredited using the same standards, they could recognize each other's decisions. Reciprocity would enable researchers with multi-site research to go to one Board only. There would be fewer delays; researchers could proceed with their research more quickly and efficiently.

Accreditation would also increase efficiency among Research Ethics Boards within the University of Alberta. Currently, ethics review is sought from the researcher's faculty. However, it is also required from other faculties if a researcher has joint appointments and if resources from other faculties are used.[29] With higher and more consistent standards in place, review from one Research Ethics Board should be sufficient.

As well, the University of Alberta requires its own ethics review even if an outside agency or institution has already approved the research.[30] If all the institutions were accredited, they could recognize one another's decisions. Trust and political goodwill would be required among Research Ethics Boards for reciprocity to be accepted.[31]

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[29] As noted on the website of the Human Research Protections Office (HRPO), researchers should always seek review from the Research Ethics Board that represents their Faculty, and "[i]f you have joint appointments, contact the REBs of all Faculties in which you have appointments" and "[i]f you use resources of Faculties other than your own, contact the REBs of those other Faculties" (Human Research Protections Office, online: University of Alberta <http://www.uofaweb.ualberta.ca/orca/hrpo.cfm>).

[30] *Ibid.*

[31] The following example applies to research using identifiable health information. Under the terms of the *Health Information Act*, R.S.A. 2000, c. H-5, s. 48-56 [*HIA*], researchers who want to use identifiable health information from Alberta for research purposes require ethics approval from one of six designated Research Ethics Boards (see Chapter 1, footnote 36). This provision applies to researchers from both within and outside of Alberta. If an Ontario or Manitoba-based researcher, for example, wanted to use data from Alberta's Cancer Registry, he or she would have to get ethics approval from an Alberta Research Ethics Board despite already having received it from the local Research Ethics Board. If institutions with Research Ethics Boards were accredited, and providing the Alberta legislation were amended to reflect this

It may be argued that accreditation is not a necessary prerequisite to reciprocal agreements. For example, a reciprocal agreement is presently in place between the Alberta College of Physicians and Surgeons Research Ethics Board and the University of Calgary Conjoint Board. My response is that there are some useful steps being taken in this direction, however, the agreement permits each Board the discretion to allow or not allow recognition of each other's decisions. Preserving autonomy results in limited value to researchers who still end up having to go to more than one more Board, losing valuable time that could be spent doing the research.

An argument against the effectiveness of accreditation is that it is too costly in terms of the human and financial resources required to prepare for and undergo it. Further, it may be argued that tasking Research Ethics Boards with accreditation preparation and participating in site visits from accreditation teams takes valuable time which could be better used on debating ethical dilemmas and reviewing protocols.[32] I acknowledge that it is time consuming and highly labor intensive to prepare for an accreditation evaluation. However, I believe that these expenditures are worthwhile and must be viewed as a long term investment in the institution and importantly, in the preservation of human dignity.

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reality, there would be an objective basis from which to accept the extra-provincial ethics approval. The same argument applies to non-health-related research. If Research Ethics Boards outside of Alberta were accredited, Alberta Boards could recognize their decisions and not require researchers to undergo local review. In order for this to happen in practice, trust among Research Ethics Boards would be required, and institutions would have to choose to rely on decisions of their colleagues in other institutions. There may be some resistance to this notion, as Research Ethics Boards are accustomed to exercising significant amounts of autonomy.

[32] In another context, McNeill has argued against more regulations and additional formal research ethics processes in Australia: "The difficulty is that more regulation and more bureaucracy makes more work for many people, creates greater hurdles for researchers, without necessarily providing any greater protection for research participants.... To continue to treat ethics committees as instruments of bureaucratic regulation and control is to misunderstand the nature and meaning of ethics" (Paul M. McNeill, "Research Ethics Review and the Bureaucracy" (2002) 21:3 Monash Bioethics Review 72 at 73).

c) Objective

The introduction of measurable standards by which to assess institutions brings objectivity to the process. There would be measures from which to know whether Research Ethics Boards are doing an acceptable job. This would increase impartiality. That is, having the standards in place decreases the chances of bias – instead of relying on, or being perceived to rely on, bias or personal preferences, Research Ethics Board members could rely on these standards.

A skeptic might argue that the accreditation process is not actually objective because the research ethics community is so small and expertise is held by such a limited number of people that everyone is known to their colleagues and so no institution will get a truly objective assessment. My view is that is why it is so critical that the standards themselves be specific, measurable, and objective.

Someone disagreeing with accreditation might argue that the processes are already objective enough. Research Ethics Boards currently follow objective standards in the *Tri-Council Policy Statement* and university policies, among other regulations. Transparency is achieved through these policies and regulations already. Impartiality is not being compromised. My response is that the hodge-podge of regulations that govern research ethics leaves more confusion than transparency, and that accreditation affords an opportunity to bring clarity to all concerned parties.

It may be argued that standardization infringes on the autonomy of Research Ethics Boards, and by extension, academic freedom. This argument asserts that members of the academy should have the liberty and latitude to make decisions in accordance with their conscience rather than have external standards imposed on them. This is in keeping

with the tradition of collegiality for which the academy is known and respected. The academy's long and honored tradition and context is one of peer review, whether of papers for publication, or of colleagues obtaining tenure.

From this perspective, it is understandable that this strong tradition of peer review would feel resistant to external bodies dictating standards. The feeling is that they have been doing fine on their own for many years and should be left to deal with research protocols according to their own consciences and discretion.

These notions suggest that academics who have undergone rigorous training to obtain graduate degrees and enter the academy trust each other, and are able to effectively assess the protocols of one another. They have collegial relationships, so are bound to trust the judgment of their colleagues and revise their protocols accordingly, because the individuals serving on the Boards are known to one another. Indeed, it may be argued that the academic context itself is a justification for procedural defects in terms of independence and impartiality.

Collegiality, however, acts as a double-edge sword. On the positive side, it may mean that the working environment is characterized by mutual respect for colleagues putting forward protocols. On the negative side, Research Ethics Board members may feel pressured, either subconsciously or explicitly, to accept the protocols of colleagues who work in close proximity to them. There may be a reluctance to question protocols of colleagues occupying a near-by office. The objective standards associated with an accreditation process could alleviate some of the potentially negative sides of collegiality.

I disagree with the implication that the rigorous training to obtain graduate degrees, combined with the fact of being employed at an institution steeped in history,

necessarily qualifies people to serve on Research Ethics Boards. This is an erroneous conclusion. Academic training does not qualify everyone to assess difficult and complex ethical issues of protection of human subjects. It qualifies them to be experts in their field. It provides a strong foundation for teaching, research, and community service activities. It does not necessarily address ethical issues in a deep and focused way. Academic freedom is not compromised by ensuring that objective standards are set and met. Having objective standards is a step toward enhancing actual and perceived independence of Research Ethics Boards.

It is perception or appearance that matters here. Having objective standards that all institutions with Research Ethics Boards must meet brings a needed measure of predictability to the process.

2. *Accreditation Standards*

a) In General

Accreditation standards are presently under development. A sub-committee of the task force was established and has produced a report. Areas such as training of Research Ethics Boards members,[33] Research Ethics Board membership, and ensuring that Board membership follows the *Tri-Council Policy Statement* requirements will be addressed.

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[33] As the standards are developed, my view is that there should be an initial and continuing program of education, which will use resources internal and external to the University. Internal resources could include providing ethics courses by specialists in the field of ethics. External resources could include NCEHR, as well as conferences sponsored by organizations such as the Canadian Bioethics Society. The training component of the accreditation process would strengthen the impartiality of Research Ethics Boards' chairs and members. This is because the training would point to objective standards to be followed rather than an undefined sense of what is right or wrong in the circumstances. Although there is some basic training available for new chairs and members, it tends to be online and may be taken inconsistently. Although members are busy with many competing demands, in-person training would allow time for discussion and more in-depth reflection of the issues. It is a way of taking the protection of human subjects more seriously.

b) Organizational Placement

The NCEHR Report 2006 makes a brief reference to organizational placement of Research Ethics Boards in draft Standard 1, which provides that "[t]he organization [is to have] a systematic and comprehensive PEERH [Program Ensuring Ethical Research with Humans] established by the highest levels of the organization," and "the organization [is to delegate] responsibility for PEERH to an official with sufficient standing, authority and independence to ensure implementation and maintenance of the program."[34]

The development of this standard is of particular interest to me. I will elaborate on that next. My proposed reform regarding institutional independence concurrently acknowledges the need for connection with the University while allowing some healthy distance from it.

3. *Recommended Reforms*

There are two aspects I am concerned with here: (a) Organizational Placement and (b) Reporting to General Faculties Council.

a) Organizational Placement

As I explained in Chapter 3, the University of Alberta's institutional placement of the governance of research ethics falls under the jurisdiction of the Office of the Vice-President (Research), and more specifically, the Human Research Protections Office. The Provost has operational responsibility for the entire university and for "coordinating [the five Vice-Presidents, including the Vice-President (Research)'s] portfolios' initiatives and implementing strategic/budget/policy decisions of Board and President."[35]

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[34] NCEHR Report 2006, *supra* note 16 at 69.
[35] See "Senior Executive Responsibility Structure, University of Alberta – Current," Organizational Chart (Figure 2).

The University of Alberta has taken useful and constructive steps in establishing the centralized Human Research Protections Office and the faculty-based Research Facilitation Offices. However, in leaving these units under the jurisdiction of the Office of the Vice-President (Research), there remains a conflict of interest because that Office is still responsible both for protecting human research subjects and bringing research dollars into the University.

I do acknowledge that the Vice-President (Research)'s Office has an advantage as a direct report in that the position is influential enough to effect administrative or policy change. Another advantage is that the Vice-President (Research)'s Office is a senior element in the University's executive structure, which is a strategic position from which to further the research mandate.

Nonetheless, I submit that the President's Office is better than the Office of the Vice-President (Research) for reporting purposes because one of the latter's main functions is ensuring that research monies continue to flow into the University. I acknowledge that the President, too, would have an interest in receiving research funds. However, the President's Office is not mandated primarily to bring research dollars into the University, but rather is tasked with overall governance issues. The budget of the Office of the President does not directly support research ventures in the same manner as the Office of the Vice-President (Research). Consequently, the conflicts of interest are less troublesome for the President's Office.

The unit which coordinates the Research Ethics Boards has to be located somewhere, for the purposes of budget, staffing, and related matters. Although the President's Office currently does not have any direct functional reports (see the

organizational chart in Figure 4), an exception should be made in the case of research ethics. The office governing research ethics should be attached to the President's Office, as shown in Figure 5. Having the Research Ethics Boards' coordinating unit report to the President directly removes the function from the University's main administrative structure, while maintaining the needed institutional link.

The unique nature of the protection of human subjects makes this critical, despite the fact that the President may prefer to delegate the daily running of the University to the Provost. At other universities, Presidents have direct reports. What I am proposing is more of an attachment than a direct report, since the formal reporting would be to General Faculties Council. It is reasonable in these circumstances to follow this course of action, given the need for Research Ethics Boards to be both attached to, and detached from, the University.

b) Reporting to General Faculties Council

Research Ethics Boards should report directly to General Faculties Council annually. General Faculties Council includes a broad cross-section of University membership and receiving the reports would allow representatives from across campus to be informed about research ethics. The role of protecting human research subjects is so important and so unique that strong measures are needed to demonstrate clarity and transparency to the reasonable person assessing the University's institutional structure. This model maintains an appropriate separation of the branches of governance, with the roles of each being clearly established, supporting the principle of transparency. The judicial branch (the Research Ethics Board itself) would receive administrative and policy direction from the executive branch (the Human Resource Protection Office which

comes under the jurisdiction of the President's Office), and would complete the loop by reporting to the legislative branch (General Faculties Council and the Board of Governors). The unit would not be a standing committee of General Faculties Council.[36] The reporting to General Faculties Council should be like the Employment Equity Annual Reports on *Opening Doors* that were received by General Faculties Council.[37]

There is precedent for the model of a sensitive judicial or quasi-judicial tribunal reporting to the legislative branch. For example, the Office of the Information and Privacy Commissioner of Alberta, which has the authority to investigate privacy breaches under the *Health Information Act*[38] and the *Freedom of Information and Protection of Privacy Act*,[39] reports annually to the Alberta legislature. As well, the federal Canadian Human Rights Commission, which investigates complaints of discrimination and harassment under the *Canadian Human Rights Act*,[40] reports directly to Parliament on an annual basis. Another analogy to the proposed ethics reporting is the public reporting of judges' decisions. Publicity promotes openness and transparency. As such, it furthers the principles of judicial independence.

It may be argued that General Faculties Council is not an appropriate body to receive reports because the membership is insufficiently qualified to receive them. Although senior administration, faculty members, and some graduate students are well placed to receive and understand the reports, it may be argued that there are many

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[36] Standing Committees have been established by General Faculties Council to assist General Faculties Council in carrying out its responsibilities under the *Post-Secondary Learning Act*, S.A. 2003, c. P-19.5 [*PSLA*], s. 26(1), over "academic affairs." See *GFC Standing Committees and Related Bodies: Procedure, Eligibility and General Requirements*, General Faculties Council (GFC) Policy Manual (2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/gfcpolicymanual>, s. 60.
[37] Such reports were tabled between 1995 and 2000.
[38] *HIA*, *supra* note 31.
[39] *Freedom of Information and Protection of Privacy Act*, R.S.A. 2000, c. F-25.
[40] *Canadian Human Rights Act*, R.S.C. 1985, c. H-6.

undergraduate students who are unable to appreciate the nuances and complexities of such a report.[41] In my view, this is not a barrier, but rather an opportunity to educate a diverse cross section of university students about ethics issues and considerations.

In addition, undergraduate students may be future researchers, and already are potentially informed members of the public. They too are bound by research policies, as their research involving humans must also undergo Research Ethics Board review, whether regular or expedited. Having a broad and diverse audience for the report places an additional onus on the Research Ethics Boards to be clear and transparent, and to use clear language.

General Faculties Council has broad powers, as it is responsible for the academic affairs of the university. As such, research ethics falls clearly within this jurisdiction. General Faculties Council is a broadly representative body whose composition is governed by the *Post-Secondary Learning Act.*[42] A number of persons are members due to the offices they hold, including the president, who is the chair, the vice-presidents, the deans, the directors of schools, the chief librarian, the director of extension, and the registrar.[43] There are also a number of elected members of faculty councils. The registrar establishes the total number of elected members based on the number of academic staff of faculties.[44]

The reporting mechanism should be a minimum of an annual report containing a summary of the number and nature of protocols for the year. It should include ethical

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[41] The Vice-President (Academic) of the Students' Union noted that undergraduate students constitute 1/3 of General Faculties Council membership (online: University of Alberta <http://www.su.ualberta.ca/su/student_government/executive_committee/vpacademic>.
[42] *PSLA*, *supra* note 36, s. 26(1).
[43] *Ibid.*, s. 23(a).
[44] *Ibid.*, s. 24(2).

themes or dilemmas that emerged, appropriately anonymized with regard to the subject matter, investigator, and faculty. Best practices to be employed in dealing with the ethical themes or dilemmas should also be included. These reports should be general ones, and should not include specific reporting of adverse events, although if a number of adverse events have arisen, that would appear among the ethical themes.[45]

In addition, General Faculties Council should be authorized to request and receive semi-annual or quarterly reports at its discretion if questions arise in the annual report that suggest sensitivities or that human subjects may be at risk.

The annual reports of the Research Ethics Boards would go from General Faculties Council to the Board of Governors, the highest governing body of the University, for information and to promote an awareness of research ethics issues by the public. Most Board members are not versed in research ethics – that is not their area of specialty. The purpose of the Board receiving the reports is to encourage the public toward an awareness and understanding of the issues. The public, or reasonable person, need not be familiar with all the complexities of research ethics, but has a right to an overall awareness and to related opinions.[46] One subset of the public is research subjects themselves, and they have the right to be well informed in this area as well.[47] The media,

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[45] "Adverse events" refers to negative events that occur that harm human subjects as a direct result of research. They can range from physical events, such as unexpected mild side effects of drugs, to death. Adverse events raise the broader complex issue of monitoring. These issues are examined in their own body of literature, and are not the focus of this thesis.

[46] The Canadian and American public's interest in research, particularly with regard to science and technology, has been well documented (see National Science Board, "Chapter 7: Science and Technology: Public Attitudes and Technology" *Science and Engineering Indicators 2006*, online: National Science Foundation <http://www.nsf.gov/statistics/seind06/c7/c7h.htm> and Amber Lepage-Monette, "Survey Says: Public opinion on biotechnology is no longer a secret," online: Bioscienceworld: Insights for the Life Sciences Industry <http://www.bioscienceworld.ca/SurveySays>).

[47] A related question is about research subjects receiving results of the study in which they participated. This is an area that needs to be developed in Canada. A recent study showed that many Research Ethics Boards in Canada do not have guidelines requiring the reporting of study results to participants. This was identified as an ethical shortcoming. S.D. MacNeil & C.V. Fernandez, "Informing Research Participants of

both on campus and external to campus, should also be encouraged to provide coverage of these reports. At the moment only cases of unethical behavior receive media coverage, and that coverage is quite limited. Taken together, these efforts would address transparency and accountability of Research Ethics Boards processes and decisions, and thereby support the independence and impartiality of Research Ethics Boards.

4. *Conclusion*

In summary, accreditation of Research Ethics Boards enhances their independence by introducing objective standards which are recognized as having been met by accredited institutions. Standards are key to ensuring high quality, consistent decisions of Research Ethics Boards. Standards increase impartiality, both in appearance and practice, because Research Ethics Board members must make their decisions based on the merits of the case rather than on insufficiently defined *Tri-Council Policy Statement*[48] criteria or personal bias.

Research Results: Analysis of Canadian University Based Research Ethics Board Policies" (2006) 32 Journal of Medical Ethics 49.

[48] *Supra* note 2.

V. Conclusion

The rule of law requires an independent and impartial judiciary, whether the forum is a court of law, a statutory tribunal, or another body such as a Research Ethics Board. Regardless of the nature of the decision-making body, it is in the public interest that justice be done and be seen to be done. As long as Research Ethics Boards and research ethics administration, whose mandates are to ensure protection of human subjects in research, are attached to the very office whose purpose is to seek out and receive research funds, justice cannot be seen to be done. The inherent conflicts of interest demand an alternate structure. The process of accreditation by an independent, effective, and objective body that is arms length from, and external to, the institution offers needed reform to the governance of ethics review.

In this thesis, I have offered a critique of current institutional and organizational structures as a point of departure for further discussion and reflection. The United Kingdom has already moved to a system of accreditation of Research Ethics Boards. The United States has started to accredit its boards as well. As the Canadian research ethics community prepares to implement its accreditation system, it should take the legal principles of judicial independence and impartiality to heart, and apply them with rigor to the development of accreditation standards.

VI. Figures

A. Figure 1 – The Three Branches of Governance – University of Alberta

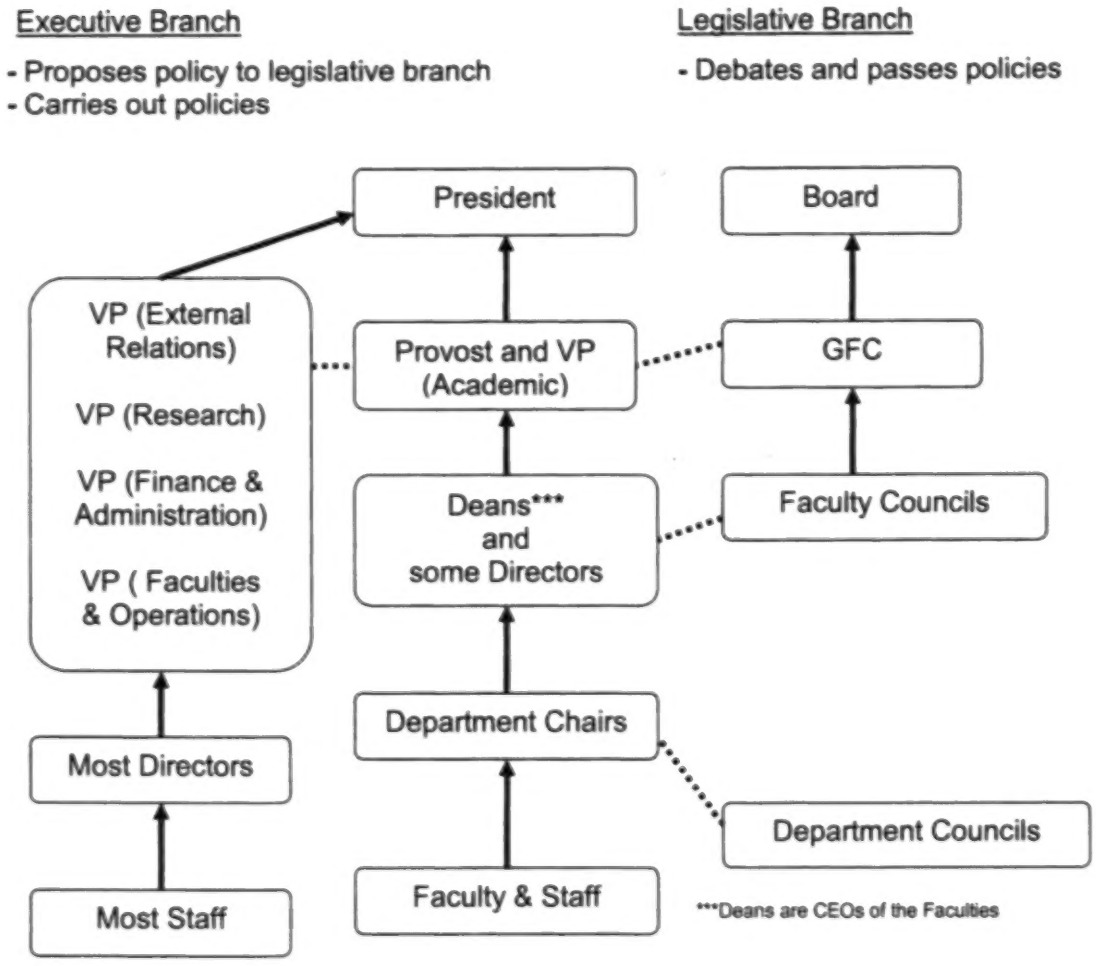
B. Figure 2 – Senior Executive Responsibility Structure, University of Alberta – Current (Organizational Chart)

C. Figure 3 – Office of the Vice-President (Research), University of Alberta – Current (Organizational Chart)

D. Figure 4 – Office of the President, University of Alberta – Current (Organizational Chart)

E. Figure 5 – Structure for Research Ethics Governance, University of Alberta – Proposed (Organizational Chart)

A. Figure 1 – The Three Branches of Governance – University of Alberta*



Judicial Branch

Students (GFC)
- Academic Standing
- Discipline
- Practicum placement/Safety

Academic Staff (Board of Governors)
- Article 16 of Board/ AAS:UA Agreement (Re Discipline)
- General Appeals Committee (GAC)** (Re Tenure/Increments)

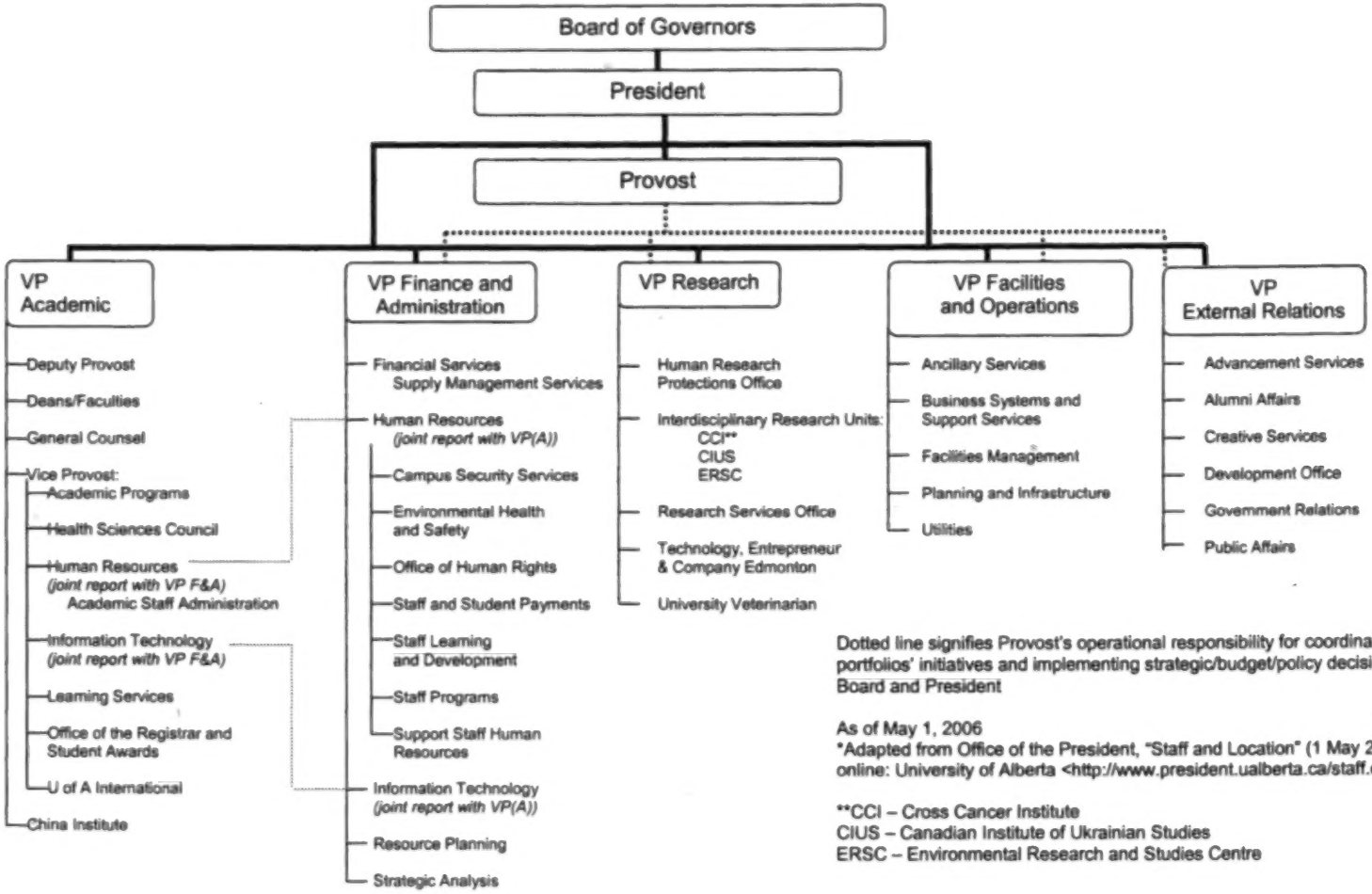
Non – Academic Staff (Board of Governors)
- Discipline and grievance Articles of Board/ NASA Agreements

Research Ethics Boards**

AAS:UA – Association of the Academic Staff: University of Alberta
CEO – Chief Executive Officer
GFC – General Faculties Council
NASA – Non-Academic Staff Association

*Adapted from University Secretariat, "Governance 101 Overview Materials – Branches of Governance" (April 2006), online: University of Alberta <http://www.uofaweb.ualberta.ca/secretariat/governance101.cfm>.
**These entries added by the author.

B. Figure 2 – Senior Executive Responsibility Structure, University of Alberta – Current (Organizational Chart)*

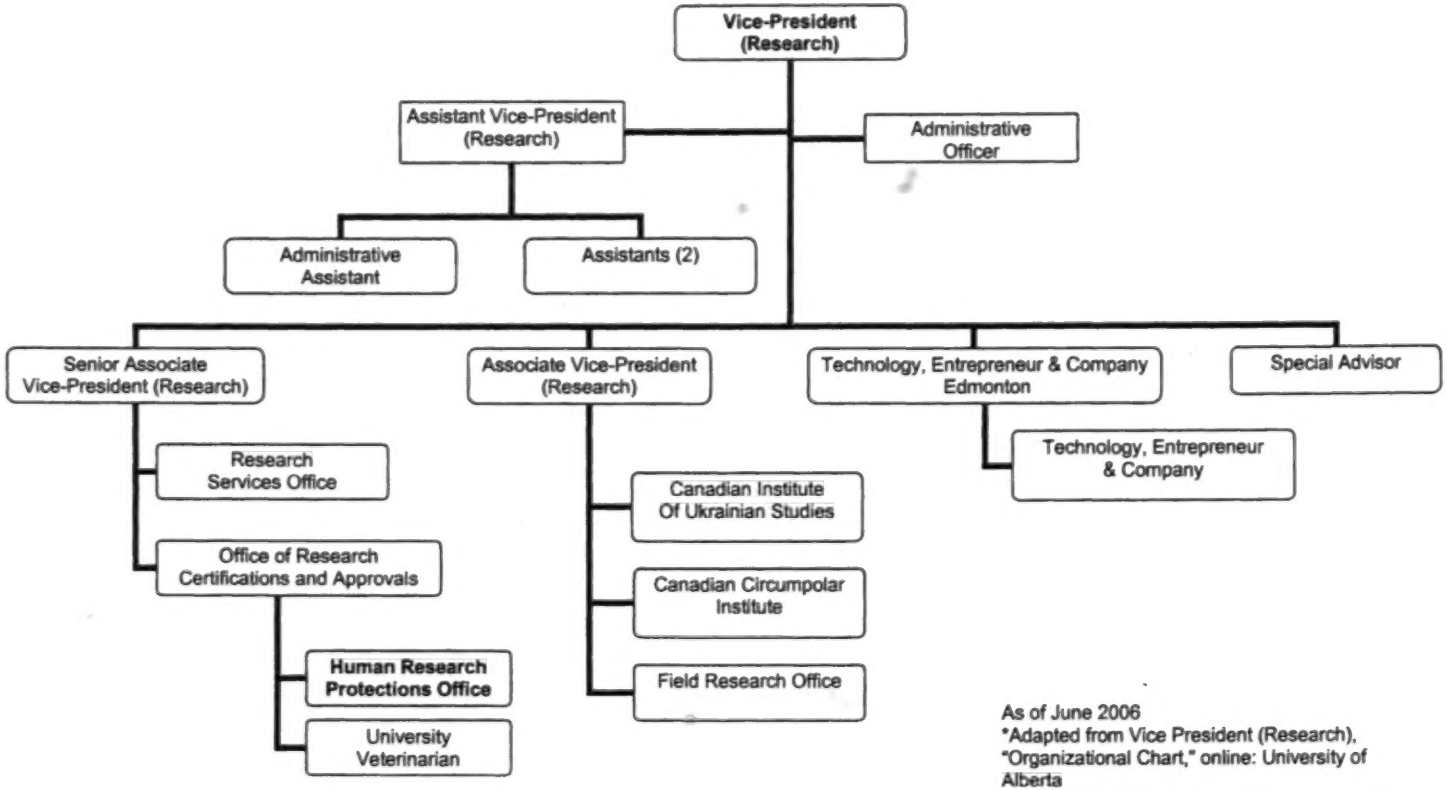


Dotted line signifies Provost's operational responsibility for coordinating portfolios' initiatives and implementing strategic/budget/policy decisions of Board and President

As of May 1, 2006
*Adapted from Office of the President, "Staff and Location" (1 May 2006), online: University of Alberta <http://www.president.ualberta.ca/staff.cfm>.

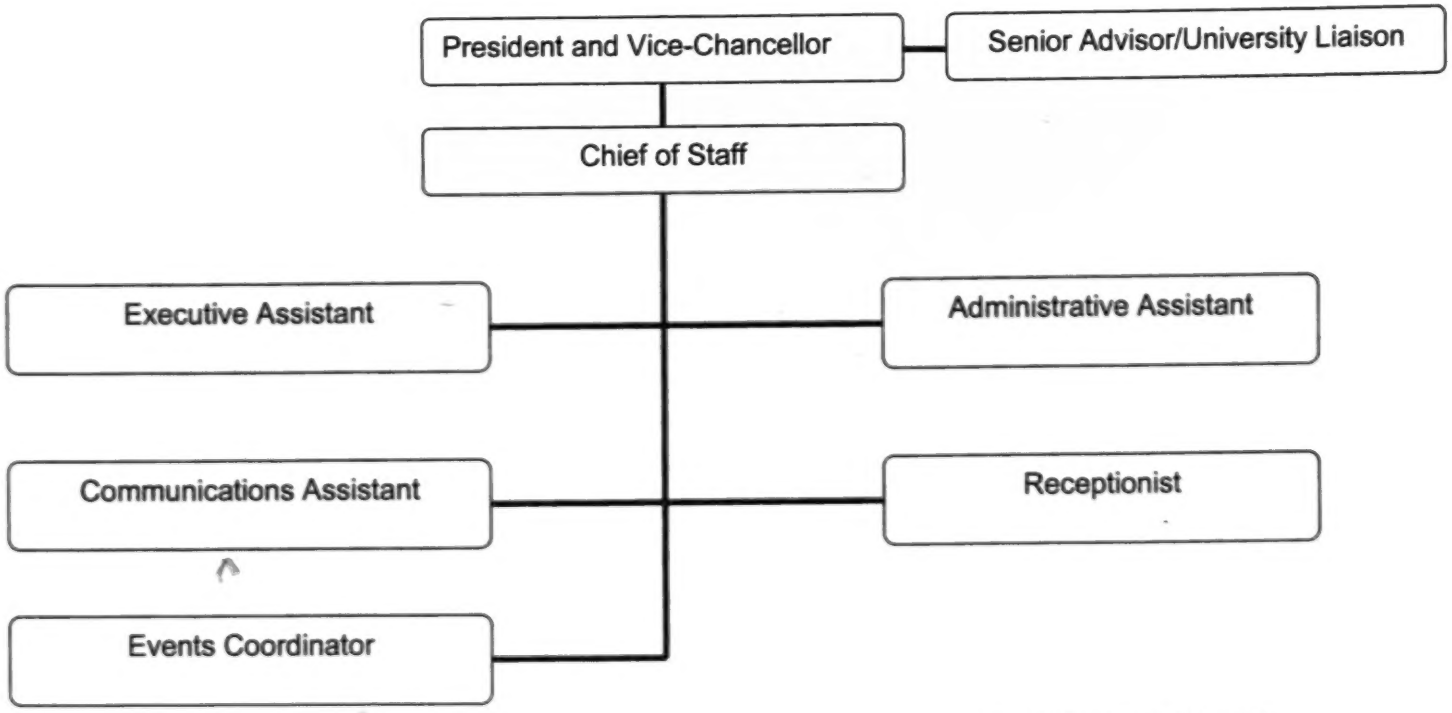
**CCI – Cross Cancer Institute
CIUS – Canadian Institute of Ukrainian Studies
ERSC – Environmental Research and Studies Centre

C. Figure 3 – Office of the Vice-President (Research), University of Alberta – Current (Organizational Chart)*



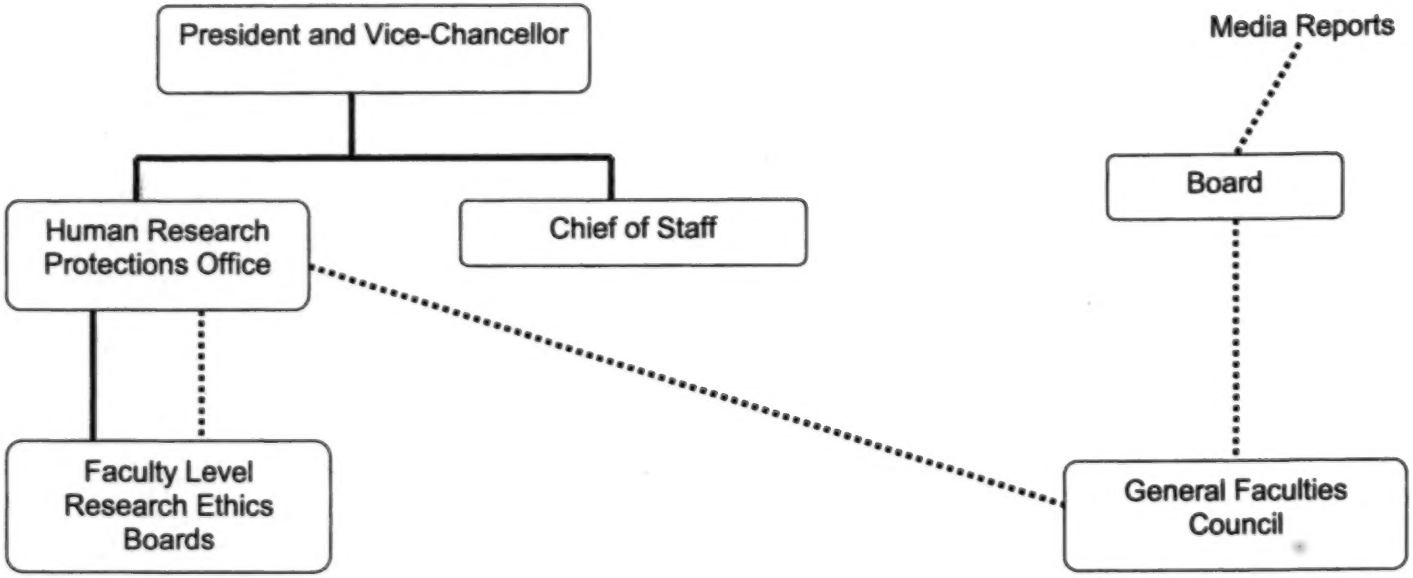
As of June 2006
*Adapted from Vice President (Research), "Organizational Chart," online: University of Alberta <http://www.uofaweb.ualberta.ca/vpresearch>.

D. Figure 4 – Office of the President, University of Alberta – Current (Organizational Chart)*



Organizational Chart 2005 – 2006
*Adapted from Office of the President, "Staff and Location," online: University of Alberta <http://www.president.ualberta.ca/staff.cfm>.

E. Figure 5 – Structure for Research Ethics Governance, University of Alberta – Proposed (Organizational Chart)


President and Vice-Chancellor
Media Reports
Board
Human Research Protections Office
Chief of Staff
Faculty Level Research Ethics Boards
General Faculties Council
Dotted line signifies path of Human Research Protections Office and Research Ethics Boards' Annual Report.

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